

EXHIBIT 17

CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: ACETAMINOPHEN -) MDL No. 3043
ASD-ADHD PRODUCTS)
LIABILITY LITIGATION) Case No.
) 1:22-md-03043-DLC
THIS DOCUMENT RELATES TO:)
) JUDGE DENISE
All Cases, 1:22-md-03043) COTE

FRIDAY, AUGUST 11, 2023

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Videotaped deposition of Brandon Pearson, MS, Ph.D., held at the offices of Lanier Law Firm, 126 East 56th Street, New York, New York, commencing at 8:44 a.m. Eastern, on the above date, before Carrie A. Campbell, Registered Diplomate Reporter, Certified Realtime Reporter, Illinois, California & Texas Certified Shorthand Reporter, Missouri, Kansas, Louisiana & New Jersey Certified Court Reporter.

- - -

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1	71	"Differential Gene Expression Patterns in Developing Sexually Dimorphic Rat Brain Regions Exposed to Antiandrogenic, Estrogenic, or Complex Endocrine Disruptor Mixtures: Glutamatergic Synapses as Target," Lichtensteiger, et al.	135	1	(Exhibits attached to the deposition.)
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5	73	"Spatial Glutathione and Cysteine Distribution and Chemical Modulation in the Early Organogenesis-Stage Rat Conceptus in Utero," Beck, et al.	166	5	ERRATA.....303
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12	77	Pages 325 to 326 of Dr. Cabrera's deposition	218	12	
13	78	"Examining associations between prenatal biomarkers of oxidative stress and ASD-related outcomes using quartile regression," Carey, et al.	253	13	
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15	79	"Perinatal Acetaminophen Exposure and Childhood Attention-Deficit/Hyperactivity Disorder (ADHD): Exploring the Role of Umbilical Cord Plasma Metabolites in Oxidative Stress Pathways," Anand, et al.	258	15	
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1	80	"The valproic acid-induced rodent model of autism," Nicolini, et al.	264	1	VIDEOGRAPHER: We are now on the record. My name is Jonathan
2				2	Juarez. I am a legal videographer for
3	81	"A comprehensive weight of evidence assessment of published acetaminophen genotoxicity data: Implications for its carcinogenic hazard potential," Kirkland, et al.	265	3	Golkow Litigation Services.
4				4	Today's date is August 11,
5				5	2023, and the time is 8:44 a.m.
6	82	"Paracetamol (Acetaminophen) Administration During Neonatal Brain Development Affects Cognitive Function and Alters Its Analgesic and Anxiolytic Response in Adult Male Mice," Viberg, et al.	276	6	This deposition is taking place
7				7	at 126 East 56th Street, New York,
8				8	New York, in the matter of
9				9	Acetaminophen (Tylenol) Products
10	83	"Early paracetamol exposure decreases brain-derived neurotrophic factor (BDNF) in striatum and affects social behaviour and exploration in rats," Blecharz-Klin, et al.	276	10	Liability Litigation.
11				11	The deponent is Brandon
12	84	"A Cannabinoid Receptor Type 1 (CB1R) Agonist Enhances the Developmental Neurotoxicity of Acetaminophen (Paracetamol), Philippot, et al.	277	12	Pearson.
13				13	All counsel will be noted on
14	85	"Effect of prenatal and early life paracetamol exposure on the level of neurotransmitters in rats-Focus on the spinal cord," Blecharz-Klin, et al.	277	14	the stenographic record.
15				15	The court reporter is Carrie
16				16	Campbell and will now swear in the
17	86	"Cerebellar level of neurotransmitters in rats exposed to paracetamol during development," Blecharz-Klin, et al.	278	17	witness.
18				18	
19				19	
20	87	"Hypothalamus - Response to early paracetamol exposure in male rats offspring," Blecharz-Klin, et al.	278	20	BRANDON PEARSON, MS, Ph.D.,
21				21	of lawful age, having been first duly sworn
22				22	to tell the truth, the whole truth and
23	88	NIH Grants & Funding printout	285	23	nothing but the truth, deposes and says on
24				24	behalf of the Defendant Johnson & Johnson, as
25				25	follows:

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<p>1 DIRECT EXAMINATION</p> <p>2 QUESTIONS BY MR. PADGETT:</p> <p>3 Q. Good morning.</p> <p>4 A. Good morning.</p> <p>5 Q. Can you state your full name</p> <p>6 for the record, please?</p> <p>7 A. Brandon Lance Pearson.</p> <p>8 Q. Okay. And you have a Ph.D.?</p> <p>9 A. I do.</p> <p>10 Q. Okay. Have you even been</p> <p>11 deposed before?</p> <p>12 A. I have not been deposed before.</p> <p>13 Q. Okay. Just a quick rundown of</p> <p>14 some basic ground rules.</p> <p>15 You understand that the oath</p> <p>16 you just took is the same one as if you were</p> <p>17 in a court of law?</p> <p>18 A. I do understand this.</p> <p>19 Q. Okay. And not a marathon</p> <p>20 session. We'll probably take breaks every 60</p> <p>21 to 90 minutes.</p> <p>22 Does that sound good to you?</p> <p>23 A. I understand.</p> <p>24 Q. Okay. And probably the number</p> <p>25 one rule today is that -- I'm going to make a</p>	<p>1 those that were part of your weight of</p> <p>2 analysis in your expert report?</p> <p>3 A. I do not believe we brought</p> <p>4 anything in addition to that.</p> <p>5 Q. Okay. Are there any notes --</p> <p>6 any of your notes on those studies that you</p> <p>7 brought with you in this room today?</p> <p>8 A. No.</p> <p>9 Q. Okay. They're clean copies?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. At a break, is it -- we</p> <p>12 may take a peek at them.</p> <p>13 MS. HUNT: Be my guest.</p> <p>14 QUESTIONS BY MR. PADGETT:</p> <p>15 Q. Okay. Any other documents that</p> <p>16 you brought with you today, other than your</p> <p>17 report and those studies you just discussed?</p> <p>18 A. No.</p> <p>19 (Pearson Exhibit 64 marked for</p> <p>20 identification.)</p> <p>21 QUESTIONS BY MR. PADGETT:</p> <p>22 Q. Okay. I'm going to hand you</p> <p>23 what's been marked, Dr. Pearson, as Exhibit</p> <p>24 Number 64.</p> <p>25 Do you recognize that document?</p>
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<p>1 deal. I'm going to try not to start a</p> <p>2 question before you finish your answer, and</p> <p>3 in return, hopefully you'll not start to</p> <p>4 answer until I'm done with my question.</p> <p>5 Does that sound like a fair</p> <p>6 deal?</p> <p>7 A. That's fair.</p> <p>8 Q. Okay. Did you bring any</p> <p>9 documents with you in the room today?</p> <p>10 A. I have a copy of my expert</p> <p>11 report, my amended expert report, and with us</p> <p>12 we have copies of the studies that were</p> <p>13 reviewed as part of my expert report.</p> <p>14 Q. When you say -- so all of the</p> <p>15 studies that you have with you, and I saw a</p> <p>16 box brought in, are studies that are</p> <p>17 discussed in your expert report?</p> <p>18 A. The studies that were a</p> <p>19 component of the weight of evidence for the</p> <p>20 levels of evidence.</p> <p>21 Q. I believe that was like 29</p> <p>22 mouse and rat studies?</p> <p>23 A. That's the approximate number</p> <p>24 that I recall, yes.</p> <p>25 Q. Okay. Any other studies beyond</p>	<p>1 A. Yes.</p> <p>2 Q. Okay. And that is your</p> <p>3 July 19, 2023 invoice for your work in this</p> <p>4 case, correct?</p> <p>5 A. That appears to be what this</p> <p>6 is.</p> <p>7 Q. And this will kind of -- may</p> <p>8 short-circuit some of my questions.</p> <p>9 There's a reference down there</p> <p>10 for 6/14 and a description of your activities</p> <p>11 that day.</p> <p>12 Do you see that? June 14?</p> <p>13 A. Yes, there's a couple of lines</p> <p>14 that say 6/14.</p> <p>15 Q. Oh, okay. The first one, I'm</p> <p>16 looking at.</p> <p>17 A. Okay.</p> <p>18 Q. You reference there a 30-minute</p> <p>19 morning meeting with Amanda Hunt, and that's</p> <p>20 counsel sitting next to you, right?</p> <p>21 A. Yes.</p> <p>22 Q. But then it says 1:45-minute</p> <p>23 meeting with Dr. Cabrera and 1:15-minute</p> <p>24 meeting with Dr. Louie to discuss contents of</p> <p>25 expert reports.</p>

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<p>1 Was counsel present for the</p> <p>2 meeting -- meetings with Dr. Cabrera and</p> <p>3 Dr. Louie?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. Have you had any</p> <p>6 meetings or Zoom -- Zooms or calls with</p> <p>7 plaintiffs' other named experts in this case</p> <p>8 in which counsel was not present?</p> <p>9 A. Are you asking about</p> <p>10 Dr. Cabrera or Dr. Louie specifically or</p> <p>11 other --</p> <p>12 Q. No, you've already clarified</p> <p>13 that -- any of them.</p> <p>14 A. Any other expert reports</p> <p>15 involved in this case or these specific</p> <p>16 expert reports?</p> <p>17 Q. No. There's four other experts</p> <p>18 named: Dr. Cabrera, Dr. Baccarelli,</p> <p>19 Dr. Louie and Dr. Hollander, right?</p> <p>20 A. So Dr. Baccarelli I would have</p> <p>21 had meetings with independent of counsel.</p> <p>22 Q. And did you have meetings with</p> <p>23 him discussing this case?</p> <p>24 A. No.</p> <p>25 Q. Did you have meetings with any</p>	<p>1 objection to form only. But he could</p> <p>2 have clarified that if he didn't</p> <p>3 understand.</p> <p>4 QUESTIONS BY MR. PADGETT:</p> <p>5 Q. Can you -- I'll rephrase.</p> <p>6 Have you had any written</p> <p>7 communications with any of other --</p> <p>8 plaintiffs' other disclosed experts in this</p> <p>9 case regarding your work on this litigation,</p> <p>10 your expert report or their expert reports,</p> <p>11 in which plaintiffs' counsel was not</p> <p>12 involved?</p> <p>13 A. Not to my recollection. If</p> <p>14 that did exist, it would have been produced.</p> <p>15 Q. In response to the request for</p> <p>16 production that was part of your deposition</p> <p>17 notice?</p> <p>18 A. Yes. But as I stated, I don't</p> <p>19 believe that exists.</p> <p>20 Q. Okay.</p> <p>21 A. I don't believe any of that</p> <p>22 correspondence exists.</p> <p>23 Q. How did you initially get</p> <p>24 involved in this case, Dr. Pearson?</p> <p>25 A. I was contacted by Amanda</p>
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<p>1 other of the named experts we just went</p> <p>2 through about your work on this case or your</p> <p>3 expert report or their expert reports in the</p> <p>4 absence of plaintiffs' counsel?</p> <p>5 A. No.</p> <p>6 Q. Okay. Have you had any written</p> <p>7 communications with any of plaintiffs' other</p> <p>8 named experts in this case in which</p> <p>9 plaintiffs' counsel were not copied or</p> <p>10 somehow address -- addressees?</p> <p>11 A. Could you -- could you state</p> <p>12 that again please?</p> <p>13 Q. Have you had any written</p> <p>14 communications with any of the other named</p> <p>15 plaintiffs' counsel in this case involving</p> <p>16 your work on this case or your expert reports</p> <p>17 or their expert reports that did not include</p> <p>18 plaintiffs' counsel?</p> <p>19 MS. HUNT: Object to form. I</p> <p>20 think you said plaintiffs' counsel and</p> <p>21 then plaintiffs' experts.</p> <p>22 MR. PADGETT: Thank you.</p> <p>23 Just -- I want to go back to</p> <p>24 the -- I understand you're clarifying,</p> <p>25 but there is a strict rule on</p>	<p>1 directly.</p> <p>2 Q. And that was your first contact</p> <p>3 about this litigation?</p> <p>4 A. Correct.</p> <p>5 Q. And when was that contact first</p> <p>6 made?</p> <p>7 A. If my memory serves, it was</p> <p>8 approximately February of this year? Or</p> <p>9 2022. Sorry, my -- yeah, February.</p> <p>10 Q. February of this year? 2023?</p> <p>11 A. Sorry, no. February of 2022.</p> <p>12 It would be in the e-mails that</p> <p>13 were produced.</p> <p>14 Yeah, that timeline might --</p> <p>15 I'm a little shaky on the line right now,</p> <p>16 but --</p> <p>17 Q. So -- sorry.</p> <p>18 A. Yeah. It would have been -- I</p> <p>19 remember the month was February. Yeah, it</p> <p>20 would have been -- sorry.</p> <p>21 February of 2022 I was</p> <p>22 initially contacted. I didn't start working</p> <p>23 with the plaintiffs' attorneys until, I</p> <p>24 believe, November, which, yeah, that would</p> <p>25 have had to have been 2022. It's 2023 now.</p>

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<p>1 Q. So you were initially contacted 2 about this case in February of 2022, about 3 16 months ago?</p> <p>4 A. That's my recollection.</p> <p>5 Q. When was -- and you were 6 coauthor on a paper, a study article, that 7 was published, the Baker 2023 study; is that 8 right?</p> <p>9 A. Yes.</p> <p>10 Q. When was that article submitted 11 for publication?</p> <p>12 A. I do not recall the exact -- 13 exactly when that paper was submitted for 14 publication. I would have to look.</p> <p>15 Q. Was it submitted for 16 publication after February 2022?</p> <p>17 A. No. I do not believe it was.</p> <p>18 Q. And I believe we saw -- I 19 totaled up your invoices, and it came, 20 between your time and your hourly rate, which 21 is \$450, to about \$61,000 invoiced so far.</p> <p>22 Does that sound about right?</p> <p>23 A. My hourly rate is \$400.</p> <p>24 Q. Oh, sorry.</p> <p>25 A. And I haven't tallied the total</p>	<p>1 A. -- the rebuttal report?</p> <p>2 Q. The rebuttal report. Sorry.</p> <p>3 A. I can't say for certainty, but 4 that would include that time. That 50 to 5 100 hours would include that time. 6 (Pearson Exhibit 65 marked for 7 identification.)</p> <p>8 QUESTIONS BY MR. PADGETT:</p> <p>9 Q. Dr. Pearson, I'm going to hand 10 you what's been marked as Exhibit 65, which I 11 believe is the same thing as the report -- 12 the amended report that you have in front of 13 you.</p> <p>14 Can you confirm that that is 15 your -- a copy of your June 21 amended expert 16 report in this case?</p> <p>17 A. Yes. 18 (Pearson Exhibit 66 marked for 19 identification.)</p> <p>20 QUESTIONS BY MR. PADGETT:</p> <p>21 Q. And I'm going to hand you also 22 what's been marked as Exhibit 66 and ask you 23 to confirm that that's your supplemental 24 expert report relating to the Klein 2023 25 study.</p>
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<p>1 amount, but that number is probably not 2 outside the realm of possibility.</p> <p>3 Q. So the last time entry I saw on 4 your invoice was June 28.</p> <p>5 How much more time have you 6 spent working on this litigation since 7 June 28?</p> <p>8 A. I haven't sat down and 9 calculated that number.</p> <p>10 Q. Can you give me an estimate 11 since June 28?</p> <p>12 MS. HUNT: Object to form. 13 You can answer.</p> <p>14 THE WITNESS: In the month of 15 July and now into August, I would 16 estimate, I mean, many dozens of 17 hours.</p> <p>18 Somewhere between 50 and a 19 hundred, I would estimate.</p> <p>20 QUESTIONS BY MR. PADGETT:</p> <p>21 Q. And how much time was spent 22 working on your reply report of the 50 to 23 100 hours?</p> <p>24 A. You're asking me about --</p> <p>25 Q. Your rebuttal report.</p>	<p>1 And a copy of that study is 2 attached to your supplemental report, 3 correct?</p> <p>4 A. This appears to be the 5 supplement in response to the Klein, et al., 6 paper that was published, yes. 7 (Pearson Exhibit 67 marked for 8 identification.)</p> <p>9 QUESTIONS BY MR. PADGETT:</p> <p>10 Q. And I'm going to hand you 11 what's been marked as Exhibit 67 and ask you 12 to confirm that that is your July 28, 2023 13 rebuttal report submitted in this case.</p> <p>14 A. Yes, this appears to be that 15 document.</p> <p>16 Q. Okay. And I believe your CV is 17 Exhibit A to your amended expert report, 18 Exhibit 65.</p> <p>19 Is the information on your CV 20 regarding employment and publications 21 current?</p> <p>22 A. It was current as of the date 23 that was on it, which was early June.</p> <p>24 Q. Any changes in position or 25 publications since early June 2023 with</p>

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<p>1 regard -- that you would put on your CV if</p> <p>2 you updated it?</p> <p>3 A. Are you asking if there's</p> <p>4 anything to update to date -- to now?</p> <p>5 Q. Yes.</p> <p>6 A. Certainly there's things that</p> <p>7 would be updated, yeah.</p> <p>8 Q. What about employment</p> <p>9 positions? Are you in the same employment as</p> <p>10 listed on your CV?</p> <p>11 A. My employment is the same.</p> <p>12 Q. Okay. What other changes -- do</p> <p>13 you have an updated version of your CV?</p> <p>14 A. I do not have an updated</p> <p>15 version, no.</p> <p>16 Q. So if you were asked to create</p> <p>17 a CV this coming Monday, what additional</p> <p>18 things would you put on there?</p> <p>19 A. I'm on an editorial board for</p> <p>20 another journal, for the Journal of</p> <p>21 Scientific Reports. I was appointed to</p> <p>22 that -- to the editorial board of that</p> <p>23 journal. That's new.</p> <p>24 I have another publication that</p> <p>25 was accepted in the journal Frontiers in</p>	<p>1 environmental exposures can also mutate those</p> <p>2 genes.</p> <p>3 And this particular study has</p> <p>4 evaluated the fact that exposures can also</p> <p>5 mutate those genes, and the study has</p> <p>6 garnered a lot of support for the fact that</p> <p>7 those genes are vulnerable to exposures,</p> <p>8 including things that cause oxidative stress</p> <p>9 and DNA damage.</p> <p>10 And acetaminophen causes a lot</p> <p>11 of oxidative stress and DNA damage, so in</p> <p>12 that sense it's relevant.</p> <p>13 Q. I'm sorry. What type of</p> <p>14 environmental substances were reviewed in</p> <p>15 that study?</p> <p>16 A. This particular study focuses</p> <p>17 on environmental carcinogens, so things like</p> <p>18 UV exposure, radiation, chemotherapeutic</p> <p>19 drugs, things of that nature. So things that</p> <p>20 we know can cause cancer.</p> <p>21 Q. Who are the coauthors of that</p> <p>22 study?</p> <p>23 A. So the lead author is</p> <p>24 Dr. Brennan Baker, who is also the lead</p> <p>25 author on some of the studies that are</p>
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<p>1 Neuroscience that has to do with</p> <p>2 environmental exposures and mutations and</p> <p>3 neurodevelopmental disorder genes.</p> <p>4 There's other things that I</p> <p>5 can't think of off the top of my head at the</p> <p>6 moment. That's just -- those are examples.</p> <p>7 Q. The article that was just</p> <p>8 recently accepted for publication that you</p> <p>9 just mentioned, does that relate in any way</p> <p>10 to acetaminophen?</p> <p>11 A. It has relevance for</p> <p>12 acetaminophen, but it doesn't study</p> <p>13 acetaminophen directly.</p> <p>14 Q. Can you tell me a little bit</p> <p>15 more about that particular study?</p> <p>16 A. That study evaluates how</p> <p>17 carcinogens in particular can mutate genes</p> <p>18 that are implicated in neurodevelopmental</p> <p>19 disorders.</p> <p>20 So individuals in the field of</p> <p>21 genomics and psychiatric genomics consider</p> <p>22 familial genetic risk and how alleles that</p> <p>23 are implicated in neurodevelopmental</p> <p>24 disorders are inherited, but they by and</p> <p>25 large don't consider the fact that</p>	<p>1 relevant to the acetaminophen work.</p> <p>2 There's Dr. Wendy Chung, who I</p> <p>3 see is written on your notebook there, who is</p> <p>4 a geneticist and physician.</p> <p>5 Q. Any others?</p> <p>6 A. Yeah, there's a number of other</p> <p>7 coauthors.</p> <p>8 There's a student -- a former</p> <p>9 student of mine, Mu Yang.</p> <p>10 Sarah McLarnan, who is a</p> <p>11 current doctoral student of mine, is a</p> <p>12 coauthor.</p> <p>13 Let me think about who else are</p> <p>14 coauthors on that study.</p> <p>15 Jeremy Simon, who's a</p> <p>16 bioinformatician that I've worked with for a</p> <p>17 number of years, he's at Boston Children's</p> <p>18 Hospital now. Harvard Medical School.</p> <p>19 I'm not recollecting the other</p> <p>20 coauthors of that study at the moment.</p> <p>21 Q. And I think you indicated in --</p> <p>22 likely get into this a bit later -- but</p> <p>23 you -- that the relevance to acetaminophen is</p> <p>24 oxidative stress.</p> <p>25 You mentioned that; is that</p>

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<p>1 right?</p> <p>2 A. Oxidative stress can be an</p> <p>3 indirect mutagen.</p> <p>4 Q. And in what other respects,</p> <p>5 other than this oxidative stress being an</p> <p>6 indirect mutagen, as you put it?</p> <p>7 A. That's the -- that's the</p> <p>8 relevance.</p> <p>9 Q. Are you aware of any specific</p> <p>10 scientific research showing that</p> <p>11 acetaminophen is a mutagen through an</p> <p>12 oxidative stress mechanism?</p> <p>13 A. I mean, I have unpublished data</p> <p>14 that shows that, but I don't have published</p> <p>15 data that shows that. There -- let me think</p> <p>16 for a moment.</p> <p>17 Could you restate the question</p> <p>18 again?</p> <p>19 MR. PADGETT: Can you...</p> <p>20 (Court Reporter read back</p> <p>21 question.)</p> <p>22 THE WITNESS: Most of the</p> <p>23 literature that's looked at mutagenic</p> <p>24 properties of acetaminophen has relied</p> <p>25 on assays such as the Ames test, and I</p>	<p>1 responses and say that there is</p> <p>2 substantial scientific evidence that</p> <p>3 acetaminophen causes substantial</p> <p>4 hydroxyguanosine damage, which is DNA</p> <p>5 damage.</p> <p>6 QUESTIONS BY MR. PADGETT:</p> <p>7 Q. At thera -- sorry, go ahead.</p> <p>8 A. At therapeutic doses.</p> <p>9 Q. At therapeutic doses?</p> <p>10 A. At therapeutic doses.</p> <p>11 Q. Which study is that?</p> <p>12 A. I would have to go through the</p> <p>13 studies in more detail, but let me -- if you</p> <p>14 give me just a second.</p> <p>15 There's recent study that shows</p> <p>16 a biomarker data that -- in cord blood</p> <p>17 studies that acetaminophen exposures are</p> <p>18 linked with 8-oxo hydroxyguanosine levels in</p> <p>19 cord blood. And preclinical data as well.</p> <p>20 There is hydroxyguanosine lesions associated</p> <p>21 with acetaminophen exposures in addition to</p> <p>22 that.</p> <p>23 So the biomarker data supports</p> <p>24 this. And as I mentioned, that is DNA</p> <p>25 damage. It's a form of oxidative DNA damage.</p>
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<p>1 believe such assays aren't really</p> <p>2 capable of studying the phenomena of</p> <p>3 direct mutagenesis in mammalian</p> <p>4 systems that I'm studying.</p> <p>5 The Ames test is a -- is</p> <p>6 bacterial systems, procaryotic</p> <p>7 systems. I'm studying mammalian</p> <p>8 mutagenesis systems. It's not a</p> <p>9 relevant assay system for some of the</p> <p>10 phenomenon that I'm studying.</p> <p>11 But on the other hand, this</p> <p>12 types -- type of research is in its</p> <p>13 infancy, so a lot more research that</p> <p>14 needs to be done.</p> <p>15 QUESTIONS BY MR. PADGETT:</p> <p>16 Q. The Ames test assay test</p> <p>17 results on acetaminophen are negative for</p> <p>18 mutagenicity, correct?</p> <p>19 MS. HUNT: Object to form.</p> <p>20 You can answer.</p> <p>21 THE WITNESS: My understanding</p> <p>22 is that a lot of the Ames test data</p> <p>23 are negative.</p> <p>24 But I would like to take a</p> <p>25 moment to clarify some of my previous</p>	<p>1 Q. Would you agree that pain or</p> <p>2 complications during labor can cause</p> <p>3 oxidative stress?</p> <p>4 MS. HUNT: Object to form.</p> <p>5 You can answer.</p> <p>6 THE WITNESS: I'm not aware of</p> <p>7 literature that shows that pain or</p> <p>8 complications during labor causes</p> <p>9 hydroxyguanosine damage.</p> <p>10 QUESTIONS BY MR. PADGETT:</p> <p>11 Q. My question was about oxidative</p> <p>12 stress.</p> <p>13 Are you aware of literature</p> <p>14 showing that pain or complications during</p> <p>15 labor can cause oxidative stress?</p> <p>16 MS. HUNT: Same objection.</p> <p>17 You can answer.</p> <p>18 THE WITNESS: I'd be happy to</p> <p>19 review any studies that you -- that</p> <p>20 you put in front of me that show me</p> <p>21 that, but I'm not aware of studies</p> <p>22 that show that pain or complications</p> <p>23 during labor that show</p> <p>24 hydroxyguanosine DNA damage.</p> <p>25</p>

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<p style="text-align: right;">Page 34</p> <p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. And again, you keep saying</p> <p>3 hydroxyguanosine, and I'm saying oxidative</p> <p>4 stress generally.</p> <p>5 But -- so like my question is,</p> <p>6 are you aware of scientific literature</p> <p>7 showing that there -- the complications or</p> <p>8 pain during pregnancy can cause increased</p> <p>9 oxidative stress in a pregnant woman?</p> <p>10 MS. HUNT: Same objection.</p> <p>11 You can answer.</p> <p>12 THE WITNESS: Well, I think</p> <p>13 there's a problem with the question,</p> <p>14 because oxidative stress is a fairly</p> <p>15 diffuse term. It's kind of a very,</p> <p>16 very broad phenomenon.</p> <p>17 It's like saying stress. What</p> <p>18 is stress? What is your objective</p> <p>19 definition? It's an imbalance of</p> <p>20 antioxidant versus prooxidant systems.</p> <p>21 So you have to have operational</p> <p>22 definitions of what oxidative stress</p> <p>23 is.</p> <p>24 So if you can show me the</p> <p>25 specific studies you're referring to,</p>	<p style="text-align: right;">Page 36</p> <p>1 that pain or complications during pregnancy</p> <p>2 can cause oxidative stress.</p> <p>3 I was telling you that I don't</p> <p>4 know what you mean by oxidative stress. And</p> <p>5 I was saying hydroxyguanosine DNA lesions are</p> <p>6 a consequence of oxidative stress. That's a</p> <p>7 measurable, tangible consequence of oxidative</p> <p>8 stress that damages the DNA.</p> <p>9 I -- we can -- that's</p> <p>10 operationalizeable. We understand what that</p> <p>11 is.</p> <p>12 Q. Okay.</p> <p>13 A. And it's DNA damage, which is</p> <p>14 what we're discussing.</p> <p>15 Q. You mentioned you have</p> <p>16 unpublished data that shows -- what were you</p> <p>17 mentioning that you said you had unpublished</p> <p>18 data showing acetaminophen and oxidative --</p> <p>19 an oxidative mutagen relationship?</p> <p>20 A. Could you restate that</p> <p>21 question, please?</p> <p>22 Q. You mentioned earlier that you</p> <p>23 have unpublished data that shows -- and I</p> <p>24 believe it was in response to a question</p> <p>25 about oxidative -- oxidative mutagen type of</p>
<p style="text-align: right;">Page 35</p> <p>1 I can evaluate that. But I don't know</p> <p>2 necessarily what you're referring to,</p> <p>3 so I can't evaluate that.</p> <p>4 QUESTIONS BY MR. PADGETT:</p> <p>5 Q. Okay. Well, just to follow up</p> <p>6 on that.</p> <p>7 Stress can cause an imbalance</p> <p>8 of oxidative stress in antioxidant systems.</p> <p>9 Do you agree with that?</p> <p>10 MS. HUNT: Object to form.</p> <p>11 You can answer.</p> <p>12 THE WITNESS: Stress is a very</p> <p>13 poorly construed paradigm. I spent</p> <p>14 many years studying stress. I don't</p> <p>15 know what you mean by "stress."</p> <p>16 QUESTIONS BY MR. PADGETT:</p> <p>17 Q. In the way that you just used</p> <p>18 it and as it relates to imbalance of</p> <p>19 oxidated -- oxidative -- oxygen species and</p> <p>20 antioxidants.</p> <p>21 A. I was using that as an example</p> <p>22 of how terminology is used without a precise</p> <p>23 definition.</p> <p>24 So you're just saying that --</p> <p>25 the example that you were giving before is</p>	<p style="text-align: right;">Page 37</p> <p>1 mechanism when we were talking about the --</p> <p>2 your unpublished article has been accepted.</p> <p>3 What is that unpublished data</p> <p>4 about?</p> <p>5 MS. HUNT: Object to form.</p> <p>6 You can answer.</p> <p>7 THE WITNESS: Sorry, I didn't</p> <p>8 let you get your objection out.</p> <p>9 I'm actually really glad you</p> <p>10 asked this, because it just reminded</p> <p>11 me. We actually have published data.</p> <p>12 So in the Baker, et al., 2023</p> <p>13 paper, there is actually data that</p> <p>14 shows that there's mutational activity</p> <p>15 in it. So in the RNAC data, it shows</p> <p>16 that there's DNA damage and mutation</p> <p>17 happening. So there's cell cycle</p> <p>18 disruption. There's p53 activation</p> <p>19 that shows you there's DNA damage and</p> <p>20 cell cycle disruption.</p> <p>21 So it's not just our</p> <p>22 unpublished data. There's actually</p> <p>23 published data that shows there's DNA</p> <p>24 damage and cell cycle disruption.</p> <p>25 Our unpublished data that we</p>

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<p style="text-align: right;">Page 38</p> <p>1 had shows, and you all have seen it in 2 my production, that there's gamma-H2AX 3 in tissue that's upregulated. There's 4 53BP1 in tissue that's upregulated. 5 And you can see it. 6 There is -- so that's showing 7 you there's DNA double-strand breaks 8 in the tissue. It's showing you that 9 there's oxidative DNA damage in the 10 tissue, all caused by acetaminophen 11 exposure prenatally. 12 QUESTIONS BY MR. PADGETT: 13 Q. Are any of those related to 14 long genes? 15 A. This is -- this has nothing to 16 do with long genes. This is independent of 17 that data. 18 Q. And have any of the effects 19 that you just mentioned been specifically 20 correlated as being associated with 21 mechanisms leading to ASD? 22 A. Are you asking me with 23 reference to the mechanisms that I just 24 discussed with the DNA damage and the 25 oxidative stress?</p>	<p style="text-align: right;">Page 40</p> <p>1 these particular neurodevelopmental disorders 2 such as autism spectrum disorder. So there's 3 concordance with and correspondence with 4 those particular neurodevelopmental 5 disorders. 6 Q. You say "signatures." Are 7 those specific genetic mutations identified 8 with ASD? 9 A. No. 10 Q. Same question for ADHD. 11 And can we agree, autism 12 spectrum disorder is going -- we're going to 13 refer to it as ASD, and 14 attention/hyperactivity deficit -- 15 attention-deficit disorder we'll refer to as 16 ADHD? 17 A. Yes. 18 Q. Okay. 19 A. That would be great. 20 Q. And with re -- are there 21 specific -- with regard to the signature that 22 you just mentioned, are those specific 23 genetic mutations identified with ADHD? 24 MS. HUNT: Object to form. 25 You can answer.</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. Specific to acetaminophen. The 2 series -- starting with gamma, the series 3 like two or three that you mentioned. 4 Have any of those been 5 specifically associated with -- as a 6 mechanism leading to ASD? 7 MS. HUNT: Object to form. 8 You can answer. 9 THE WITNESS: Well, as I've 10 outlined in my expert report, the 11 oxidative stress in the tissue, the 12 DNA damage and the transcriptional 13 effects that we've seen, are 14 associated with -- and lead to 15 transcriptional signatures that 16 correspond with autism and other 17 neurodevelopmental disorders. 18 Using Gene Set Enrichment 19 Analysis and other bioinformatics 20 tools, we see enrichment with autism 21 spectrum disorder. 22 QUESTIONS BY MR. PADGETT: 23 Q. What do you mean by enrichment? 24 A. So, again, using bioinformatics 25 tools, we see signatures that correspond to</p>	<p style="text-align: right;">Page 41</p> <p>1 THE WITNESS: In the previous 2 research that I have worked on where 3 we've looked at transcriptional 4 profiles associated with these 5 exposures, excuse me, we haven't 6 necessarily looked for ADHD-relevant 7 gene expression signatures. We've 8 largely focused on ASD signatures. 9 QUESTIONS BY MR. PADGETT: 10 Q. Any other unpublished research 11 or data that you've -- that you're aware of 12 that supports a biochemical mechanism tying 13 acetaminophen to ASD or ADHD? 14 MS. HUNT: Object to form. 15 And, Bill, I apologize in 16 advance, but to the extent this gets 17 into anything currently in peer 18 review, Dr. Pearson is not going to be 19 able to answer. 20 MR. PADGETT: Understood. 21 THE WITNESS: There's nothing 22 else that I can discuss. 23 QUESTIONS BY MR. PADGETT: 24 Q. Okay. Dr. Pearson, is it your 25 opinion that any compound that causes a</p>

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<p style="text-align: right;">Page 42</p> <p>1 change or changes in the developing brain can 2 lead to an increased risk for ASD? 3 MS. HUNT: Object to form. 4 You can answer. 5 THE WITNESS: I want to make 6 sure I understand your question. 7 You're asking me whether 8 anything that can cause a change in 9 the -- in the developing brain can 10 cause risk for autism or ADHD -- ASD 11 or ADHD? 12 QUESTIONS BY MR. PADGETT: 13 Q. Increased risk, yes, correct. 14 A. I would not -- I would not 15 respond to the affirmative to that. That is 16 not my stance. 17 Q. Same question with regard to 18 ADHD. Is it your opinion that any compound 19 that causes a change or changes in the 20 developing brain can lead to an increased 21 risk for ADHD? 22 MS. HUNT: Same objection. 23 You can answer. 24 THE WITNESS: Anything that 25 leads to a change in the developing</p>	<p style="text-align: right;">Page 44</p> <p>1 types of findings that you just described may 2 be a basis for conducting further research to 3 determine a more specific relationship? 4 MS. HUNT: Object to form. 5 You can answer. 6 THE WITNESS: That's not 7 exactly what I was stating in my 8 response, but it's not incompletely 9 true what you just stated. 10 In other words, I would have to 11 qualify that response by stating that, 12 you know, responses that -- again, 13 physiologically relevant exposures in 14 the brain that affect 15 neurodevelopment, even if those 16 responses aren't specific to ASD or 17 ADHD health outcomes, 18 neurodevelopmental outcomes, again, 19 they can contribute risk for those 20 particular health outcomes in 21 individuals that are exposed within a 22 background of risk in individuals. 23 QUESTIONS BY MR. PADGETT: 24 Q. Which -- 25 A. Even if that's not the only</p>
<p style="text-align: right;">Page 43</p> <p>1 brain, any exposure that leads to a 2 change in the developing brain, does 3 not necessarily increase the risk for 4 ADHD or ASD. 5 However, things that have the 6 potential at translationally relevant 7 doses to disturb brain development 8 have to be looked at with higher 9 scrutiny for the potential effects on 10 any widespread effects. 11 So even if the effects of that 12 particular compound aren't specific to 13 ADHD or ASD, the -- it -- they can 14 exacerbate effects that are relevant 15 to ASD or ADHD. 16 In other words, if an 17 individual carries liability for ADHD 18 or ASD, those exposures may tip the 19 balance towards a particular outcome 20 even if the effects of that particular 21 exposure aren't specific to ADHD or 22 ASD risk. 23 QUESTIONS BY MR. PADGETT: 24 Q. And if those specific effects 25 aren't specific to ASD or ADHD risk, the</p>	<p style="text-align: right;">Page 45</p> <p>1 risk. Sorry. 2 Q. Which biochemical changes in 3 the embryonic or fetal human brain have been 4 identified by the scientific community as 5 known, accepted mechanisms leading to ASD? 6 MS. HUNT: Object to the form 7 of the question. 8 You can answer. 9 THE WITNESS: Could you restate 10 the question, please? 11 MR. PADGETT: Which -- can you 12 read it back, please? 13 (Court Reporter read back 14 question.) 15 THE WITNESS: You know, that 16 can't answer that question the way 17 that you've asked it because that's -- 18 that's calling to a specific, you 19 know -- that's -- you're asking me to 20 identify something that is 21 overprescriptive. In other words, 22 you're asking me to say that there's 23 one or a set of specific biochemical 24 changes that exist, when in reality 25 such conditions such as ASD and ADHD</p>

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<p style="text-align: right;">Page 46</p> <p>1 are -- involve a plethora of 2 biochemical alterations in the 3 developing brain. 4 You have to consider that the 5 developing brain is so complicated, 6 and when you have health conditions 7 such as ASD and ADHD, the com -- 8 it's -- let me take a second. It's 9 incredibly heterogeneous from 10 individual to individual. 11 And as you've had from other 12 experts that have been in this case, 13 every individual is a little bit 14 different. So you can't expect to say 15 that there's one set of biochemical 16 changes that's accepted as the, you 17 know, ASD or ADHD perturbations that 18 define that particular disorder. 19 There's set of clinical 20 perturbations that are typical to 21 these disorders but not specific to 22 these disorders. So if you were to 23 try to pin me down on one or a set of 24 those, and then an individual actually 25 in reality has different sets of those</p>	<p style="text-align: right;">Page 48</p> <p>1 in their development that you can't 2 just look on a brain scan and see. 3 But those individuals don't 4 behave completely neurotypically, so 5 you can't just define like a tumor, 6 oh, there's a tumor, and that's what 7 this individual is. 8 Essentially what you're asking 9 me to do is say, what's the tumor for 10 this individual. It's sort of an 11 unfair question. 12 QUESTIONS BY MR. PADGETT: 13 Q. You mentioned a plethora of set 14 of mechanisms. 15 Can you identify among the -- 16 that plethora those mechanisms, biochemical 17 changes, those -- strike that. 18 Can you identify among the 19 plethora that you mentioned earlier those 20 specific biochemical changes in the embryonic 21 or fetal human brain that have been 22 identified by the scientific community as 23 known, accepted mechanisms leading to ASD? 24 MS. HUNT: Object to the form 25 of the question.</p>
<p style="text-align: right;">Page 47</p> <p>1 or has something that's independent of 2 those, that's actually accepted to be 3 the case. 4 But you would try to catch 5 somebody out by saying, like, oh, 6 well, that person didn't actually have 7 this 1 or 2. That's actually an 8 unfair characterization of the biology 9 of these highly complicated and 10 heterogeneous neurodevelopmental 11 disorders. 12 I don't know how clear I was in 13 that. But what I'm trying to say is 14 that, again, it's highly 15 heterogeneous. You're dealing with 16 the most complicated organ in known 17 existence. Its development is highly 18 complicated. 19 When you -- when you think 20 about how the disorder comes to be, 21 you're dealing with a perturbation and 22 changes that are tipping the course of 23 the development to an extent to where 24 individuals aren't -- you know, can be 25 highly functional but have alterations</p>	<p style="text-align: right;">Page 49</p> <p>1 You can answer. 2 THE WITNESS: So you just asked 3 the same question. For the sake of 4 this deposition, I will go ahead and 5 start listing some. 6 So there are synaptic changes. 7 There's chromatin alterations. 8 There's columnar defects. There are 9 epigenetic changes. There are growth 10 and guidance factor alterations. 11 There's axonal guidance disruptions. 12 There are -- let me think for a 13 moment -- local hyperconnectivity, 14 large scale, global underconnectivity. 15 I mean, these are things that have 16 been replicated many times in many 17 different studies. 18 This is for autism, by the way. 19 This is not for ADHD. 20 These are the types of things 21 that you see many times that are 22 representative of autism. That 23 doesn't mean for every individual that 24 has autism that they have all of those 25 things. These are things that are in</p>

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<p>1 a bell curve. That's what's typical 2 across autism. 3 Again, it's highly 4 heterogeneous. It doesn't mean that 5 every individual that has autism has 6 those same white matter defects. That 7 doesn't mean that every individual is 8 going to have that. But those are 9 things that tend to happen. They're 10 synaptic alterations, cell adhesion 11 alterations. These are accepted 12 within the community as things that 13 are common amongst autism. 14 So when you think about 15 modeling and understanding mechanisms 16 and causality in autism, when you 17 model this preclinically and you 18 expose animals, if you expose them to 19 acetaminophen and then you see these 20 things, then there's no question that 21 there's causality. 22 QUESTIONS BY MR. PADGETT: 23 Q. The various list of things that 24 you went through, synaptic changes, 25 epigenetic changes, axonal changes, growth</p>	<p>1 MS. HUNT: Object to the form 2 of the question. 3 You can answer. 4 THE WITNESS: I would have to 5 hear that question again. I'm sorry. 6 I apologize. 7 QUESTIONS BY MR. PADGETT: 8 Q. Has the scientific community 9 identified any of those mechanisms that 10 you've just -- that you listed as generally 11 accepted changes that occur in the fetal 12 brain that lead to autism? 13 MS. HUNT: Same objection. 14 You can answer. 15 THE WITNESS: These are 16 generally accepted. As leading to 17 autism. 18 QUESTIONS BY MR. PADGETT: 19 Q. Changes in the fetal brain? 20 A. These are seen in the fetal 21 brain as well. 22 Q. Of humans? 23 A. Well, again, you can't measure 24 them in the fetal brain and then track out if 25 individuals are going to have autism or not.</p>
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<p>1 factors, those are effects seen in 2 individuals with autism spectrum disorder, 3 correct? 4 A. Yes. 5 Q. Has the scientific community 6 identified those as -- those mechanisms as 7 things seen in the fetal brain that lead to 8 autism? 9 MS. HUNT: Object to the form 10 of the question. 11 But you can answer. 12 THE WITNESS: Well, there 13 wouldn't be a method to do an 14 experiment in people to resolve 15 whether it leads to that. You know, 16 so I -- that's an absurd question. 17 I'm sorry. 18 QUESTIONS BY MR. PADGETT: 19 Q. Well, my -- let me put it this 20 way. 21 Has the scientific community 22 identified any of those mechanisms that 23 you've just listed as changes, generally 24 accepted changes, that are seen in the fetal 25 brain that lead to autism?</p>	<p>1 It's not possible to do that. 2 Q. Okay. 3 A. It's not possible to answer 4 your question the way it's asked. 5 Q. Which biochemical changes in 6 the embryonic or fetal human brain have been 7 identified by the scientific community as 8 known, accepted mechanisms leading to ADHD? 9 MS. HUNT: Object to the form 10 of the question. 11 You can answer. 12 THE WITNESS: I don't believe I 13 can answer your question. 14 QUESTIONS BY MR. PADGETT: 15 Q. You can't -- you can't answer 16 my question because you can't sit -- as you 17 sit here today identify them? 18 A. I don't think your question is 19 answerable based on logic. 20 Q. You mentioned, you know, animal 21 studies have -- you know, have shown changes. 22 Which of those changes have 23 been ident -- in the fetal human brain, which 24 of those changes have been identified by the 25 scientific community as accepted prenatal</p>

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<p style="text-align: right;">Page 54</p> <p>1 changes that lead to ADHD?</p> <p>2 MS. HUNT: Object to form.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: So you mentioned</p> <p>5 animals. Are you asking about humans</p> <p>6 or animals now?</p> <p>7 QUESTIONS BY MR. PADGETT:</p> <p>8 Q. I'm asking which of the</p> <p>9 change -- any changes seen in prenatal or,</p> <p>10 you know, up to PN 10 dosing of chemicals --</p> <p>11 of any chemical that have been shown to be</p> <p>12 mechanisms accepted by the scientific</p> <p>13 community as leading to ADHD.</p> <p>14 A. I'm sorry, I'm really confused</p> <p>15 now because you were talking about human</p> <p>16 prenatal, but now you're talking about</p> <p>17 dosing. I'm not trying to be difficult now.</p> <p>18 I just really don't understand the question</p> <p>19 now.</p> <p>20 Q. Can you identify any</p> <p>21 biochemical changes seen in any scientific</p> <p>22 research, whether human or animal, that have</p> <p>23 been -- in the fetal brain that have been</p> <p>24 accepted by the scientific community as</p> <p>25 leading to ADHD?</p>	<p style="text-align: right;">Page 56</p> <p>1 what's been marked as Exhibit 69 and</p> <p>2 represent to you this is a portion of a draft</p> <p>3 of Baker 2023 with comments from a PBL1 and a</p> <p>4 BBH2R1.</p> <p>5 Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. And it's -- PEARSON_01872 is</p> <p>8 the Bates number.</p> <p>9 Do you see that?</p> <p>10 A. I see that.</p> <p>11 Q. Okay. Are you PBL1 there?</p> <p>12 A. I am.</p> <p>13 Q. Okay. And is Brennan Baker,</p> <p>14 BBH2R1, the -- and eventually the lead author</p> <p>15 of Baker 2023?</p> <p>16 A. Yes.</p> <p>17 Q. And do you see there, the first</p> <p>18 comment says, quote, "The title needs to be</p> <p>19 more provocative or at least signal the</p> <p>20 findings better," end quote.</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And you're referring to</p> <p>24 a previous proposed title of "Effect of</p> <p>25 acetaminophen exposure during gestation and</p>
<p style="text-align: right;">Page 55</p> <p>1 MS. HUNT: Object to the form</p> <p>2 of the question.</p> <p>3 Answer, if you can.</p> <p>4 QUESTIONS BY MR. PADGETT:</p> <p>5 Q. In humans.</p> <p>6 A. I don't know how to answer your</p> <p>7 question.</p> <p>8 Q. Have you -- you know, we talked</p> <p>9 briefly about Baker 2023.</p> <p>10 Have you published any</p> <p>11 peer-reviewed articles or literature other</p> <p>12 than Baker 2023 on acetaminophen?</p> <p>13 A. I don't believe I have.</p> <p>14 (Pearson Exhibit 68 marked for</p> <p>15 identification.)</p> <p>16 QUESTIONS BY MR. PADGETT:</p> <p>17 Q. I'm going to hand you what's</p> <p>18 been marked as Exhibit 68 and ask you to</p> <p>19 confirm that's a copy of the Baker 2023</p> <p>20 study.</p> <p>21 A. It is.</p> <p>22 (Pearson Exhibit 69 marked for</p> <p>23 identification.)</p> <p>24 QUESTIONS BY MR. PADGETT:</p> <p>25 Q. Okay. I'm going to hand you</p>	<p style="text-align: right;">Page 57</p> <p>1 lactation on mouse behavior in frontal cortex</p> <p>2 gene expression," right?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And is this red your</p> <p>5 proposed new title, "Developmental</p> <p>6 acetaminophen exposure produces ADHD-like</p> <p>7 behavioral alterations in mice, paren, in a</p> <p>8 sex-dependent manner"?</p> <p>9 A. That was probably my</p> <p>10 suggestion, yes.</p> <p>11 Q. Okay. And does Mr. Baker have</p> <p>12 his Ph.D. now?</p> <p>13 A. He does, yes.</p> <p>14 Q. Okay. We'll call him</p> <p>15 Dr. Baker.</p> <p>16 And Dr. Baker responded to your</p> <p>17 comment, quote, "I don't think we can say</p> <p>18 'ADHD-like.' Can we say 'anxiety'," end</p> <p>19 quote?</p> <p>20 Do you see that?</p> <p>21 A. I see that.</p> <p>22 Q. Did you and Dr. Baker have any</p> <p>23 discussion about this particular issue</p> <p>24 offline, so to speak, about "ADHD-like" being</p> <p>25 included in the title?</p>

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<p>1 MS. HUNT: Object to form.</p> <p>2 You can answer.</p> <p>3 THE WITNESS: I don't recall.</p> <p>4 My assumption is we probably did. And</p> <p>5 I think I responded within the third</p> <p>6 title, suggestion of the third title.</p> <p>7 QUESTIONS BY MR. PADGETT:</p> <p>8 Q. Okay. And the third title is</p> <p>9 "Sex-specific neurobehavioral and frontal</p> <p>10 cortex gene expression alterations following</p> <p>11 developmental acetaminophen exposure in</p> <p>12 mice," right?</p> <p>13 A. Yes.</p> <p>14 Q. Was that -- is that where you</p> <p>15 landed?</p> <p>16 A. It's close, yeah.</p> <p>17 Q. Okay.</p> <p>18 A. It's close to where we landed,</p> <p>19 yeah.</p> <p>20 Q. And the -- so the "ADHD-like"</p> <p>21 language that you proposed is not included in</p> <p>22 the title of the published study, right?</p> <p>23 A. It was not included, yes.</p> <p>24 Q. Did Dr. Baker feel that the</p> <p>25 findings of the 20 -- Baker 2023 study did</p>	<p>1 You can answer.</p> <p>2 THE WITNESS: Dr. Baker was</p> <p>3 interested in understanding -- using a</p> <p>4 mouse model to understand ADHD-like</p> <p>5 effects of acetaminophen, yes.</p> <p>6 QUESTIONS BY MR. PADGETT:</p> <p>7 Q. And that was the impetus for</p> <p>8 the study that you -- that Dr. Baker and the</p> <p>9 rest of the team, including you, put</p> <p>10 together, right?</p> <p>11 MS. HUNT: Object to form.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: We were</p> <p>14 interested in all of</p> <p>15 neurodevelopmental effects, not just</p> <p>16 ADHD, but ADHD was a central focus.</p> <p>17 QUESTIONS BY MR. PADGETT:</p> <p>18 Q. Okay.</p> <p>19 A. Yeah.</p> <p>20 Q. Baker 2023 showed a lack of</p> <p>21 hyperactivity in treated animals, right?</p> <p>22 MS. HUNT: Object to form.</p> <p>23 You can answer.</p> <p>24 THE WITNESS: Well, there was a</p> <p>25 change in local motor activity. There</p>
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<p>1 not support using "ADHD-like" in the title?</p> <p>2 MS. HUNT: Object to form.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: You would have to</p> <p>5 ask Dr. Baker himself. I don't -- I</p> <p>6 don't want to put words in his mouth.</p> <p>7 QUESTIONS BY MR. PADGETT:</p> <p>8 Q. You don't specifically recall</p> <p>9 whether in your conversations offline, so to</p> <p>10 speak, he indicated that?</p> <p>11 MS. HUNT: Same objection.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: I don't remember</p> <p>14 if we discussed this any further.</p> <p>15 QUESTIONS BY MR. PADGETT:</p> <p>16 Q. And I've looked at some of the</p> <p>17 other background materials related -- leading</p> <p>18 up to the submission of Baker 2023 for</p> <p>19 publication.</p> <p>20 At the outset, Dr. Baker's</p> <p>21 proposed research project was focused on</p> <p>22 ADHD, right?</p> <p>23 MS. HUNT: Object to the form</p> <p>24 of the question, including the</p> <p>25 prefatory statement.</p>	<p>1 was less activity in males.</p> <p>2 QUESTIONS BY MR. PADGETT:</p> <p>3 Q. So it was the -- it was</p> <p>4 hypoactivity, the opposite of hyperactivity,</p> <p>5 correct?</p> <p>6 A. Hypoactivity.</p> <p>7 Q. Okay. So it showed a lack of</p> <p>8 hyperactivity in treated animals, correct?</p> <p>9 A. There was a disruption in</p> <p>10 activity.</p> <p>11 Q. That's not my question.</p> <p>12 Baker 2023 showed a lack of</p> <p>13 hyperactivity in treated animals, right?</p> <p>14 MS. HUNT: Object to form.</p> <p>15 You can answer.</p> <p>16 THE WITNESS: There was,</p> <p>17 strictly speaking, a lack of</p> <p>18 hyperactivity.</p> <p>19 QUESTIONS BY MR. PADGETT:</p> <p>20 Q. If you could turn to page 9 of</p> <p>21 Baker 2023. In the paragraph, the first full</p> <p>22 paragraph, first sentence, it says right</p> <p>23 there that the results demonstrate a lack of</p> <p>24 hyperactivity, right?</p> <p>25 A. Yeah, but it does not preclude</p>

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<p>1 ADHD relevance.</p> <p>2 Q. Okay. And I guess later in</p> <p>3 that paragraph there's a reference to</p> <p>4 spontaneously hyperactive rats, SHR rats --</p> <p>5 A. Yes.</p> <p>6 Q. -- show ac -- show</p> <p>7 hyperactivity, impulsivity and inattention in</p> <p>8 other tests, even though there was one study</p> <p>9 that showed them being less active in an open</p> <p>10 field test; is that right?</p> <p>11 A. Yes. It says they're less</p> <p>12 active than the Wistar Kyoto rats in the</p> <p>13 running wheel and less active in Sprague</p> <p>14 Dawley rats in open field tests.</p> <p>15 Q. Baker 2023 is a mouse study,</p> <p>16 right?</p> <p>17 A. It is a mouse study.</p> <p>18 Q. And with regard to</p> <p>19 hyperactivity, impulsivity and inattention,</p> <p>20 there was no finding consistent with those</p> <p>21 three behavioral traits for ADHD in Baker</p> <p>22 2023, correct?</p> <p>23 MS. HUNT: Object to the form</p> <p>24 of the question.</p> <p>25 You can answer.</p>	<p>1 of the question.</p> <p>2 You can answer.</p> <p>3 THE WITNESS: Well, we -- if</p> <p>4 you look at the five-choice data, even</p> <p>5 though it was not statistically</p> <p>6 significant, we only had it in a four</p> <p>7 per sex, we saw biologically</p> <p>8 potentially meaningful differences in</p> <p>9 omission data, for instance.</p> <p>10 So in panel B on Figure 6,</p> <p>11 males had higher omissions in the</p> <p>12 variable delay probe. So, for</p> <p>13 instance, Figure 6B on the third</p> <p>14 column, males had more omissions in</p> <p>15 the premature responses. They had</p> <p>16 more premature responses, which</p> <p>17 actually indicates maybe they had more</p> <p>18 impulsivity.</p> <p>19 So there's maybe some</p> <p>20 suggestions that there's some</p> <p>21 inattentiveness and some impulsivity,</p> <p>22 but we were a bit underpowered. But</p> <p>23 this was a limitation in the number of</p> <p>24 Bussey chambers, which are the</p> <p>25 operative chambers that we have access</p>
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<p>1 THE WITNESS: You're asking</p> <p>2 whether Baker 2023 had findings with</p> <p>3 respect to impulsivity,</p> <p>4 inattentiveness and hyperactivity?</p> <p>5 QUESTIONS BY MR. PADGETT:</p> <p>6 Q. Yes. Consistent with ADHD.</p> <p>7 A. Well, animal models don't have</p> <p>8 to have directional concordance to be</p> <p>9 relevant, as I state clearly in my expert</p> <p>10 report. That's a -- that's misconstruing</p> <p>11 the animal model literature.</p> <p>12 Q. I've already discussed</p> <p>13 hyperactivity.</p> <p>14 Was there any assay test in</p> <p>15 Baker 2023 in which the findings were</p> <p>16 consistent with the animal model for ADHD for</p> <p>17 impulsivity?</p> <p>18 A. We didn't look directly at</p> <p>19 impulsivity. We looked at attention and</p> <p>20 focused on attention, not impulsivity.</p> <p>21 Q. Was there any assay or test in</p> <p>22 Baker 2023 that showed a finding consistent</p> <p>23 with the ADHD animal model for -- with regard</p> <p>24 to attention?</p> <p>25 MS. HUNT: Object to the form</p>	<p>1 to.</p> <p>2 So unfortunately, in the Baker</p> <p>3 2023 paper, we just don't have enough</p> <p>4 data for the attentional and</p> <p>5 impulsivity types of measures, so more</p> <p>6 data are needed to actually say</p> <p>7 anything about attention and</p> <p>8 impulsivity.</p> <p>9 QUESTIONS BY MR. PADGETT:</p> <p>10 Q. So you're unable -- strike</p> <p>11 that.</p> <p>12 A. There might -- but there still</p> <p>13 can be meaningful pilot information that</p> <p>14 could be drawn from this study, regardless.</p> <p>15 But we were conservative about the</p> <p>16 conclusions we were trying to draw from it</p> <p>17 because it's not very statistically powered</p> <p>18 to try to draw any conclusions.</p> <p>19 Q. Can you go to the top -- the</p> <p>20 bottom of page 9, please?</p> <p>21 A. Sure.</p> <p>22 Q. And it goes -- there's a</p> <p>23 sentence that goes over to page 11, because</p> <p>24 there's a chart there.</p> <p>25 The study article specifically</p>

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<p>1 states that developmental APAP -- and can we</p> <p>2 agree that APAP is the same as acetaminophen?</p> <p>3 A. Yes.</p> <p>4 Q. "Developmental APAP exposure</p> <p>5 was not associated with mouse attention</p> <p>6 deficits in the five-choice serial-reaction</p> <p>7 task test."</p> <p>8 A. I'm not seeing what you're</p> <p>9 seeing, but I'm sure that's what we say here.</p> <p>10 Q. It's at the top of page 11.</p> <p>11 A. Okay. Yes.</p> <p>12 Q. And then you recall, I think</p> <p>13 from -- I believe it was Exhibit 69,</p> <p>14 Dr. Baker asks whether anxiety could be used</p> <p>15 in the title.</p> <p>16 With regard to anxiety, that's</p> <p>17 discussed in the conclusion of the article.</p> <p>18 Can you turn to that, please?</p> <p>19 First, I have a couple of</p> <p>20 questions about anxiety. And if you want to</p> <p>21 refer to your report, you can.</p> <p>22 But at pages 22 to 23 and 27 of</p> <p>23 your amended report, there's a discussion</p> <p>24 about the DSM-5 and neurodevelopmental</p> <p>25 disorders, including specifically with regard</p>	<p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. Anxiety is a symptom of</p> <p>3 numerous varied neurodevelopmental disorders.</p> <p>4 Agree?</p> <p>5 MS. HUNT: Object to form.</p> <p>6 You can answer.</p> <p>7 THE WITNESS: It may be, but</p> <p>8 not necessarily.</p> <p>9 QUESTIONS BY MR. PADGETT:</p> <p>10 Q. Do the DSM -- do you know</p> <p>11 whether the DSM criteria for ADHD includes</p> <p>12 anxiety?</p> <p>13 MS. HUNT: Object to form.</p> <p>14 You can answer.</p> <p>15 THE WITNESS: I would have to</p> <p>16 see the DSM criteria.</p> <p>17 QUESTIONS BY MR. PADGETT:</p> <p>18 Q. Okay. Did you look at the DSM</p> <p>19 criteria when you were putting your report</p> <p>20 together?</p> <p>21 MS. HUNT: Object to form.</p> <p>22 You can answer.</p> <p>23 THE WITNESS: No, I didn't look</p> <p>24 at them in detail.</p> <p>25</p>
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<p>1 to ASD and ADHD.</p> <p>2 Do you recall that?</p> <p>3 A. I'd like to get there.</p> <p>4 You said 22?</p> <p>5 Q. Yes. And 27 to 28.</p> <p>6 A. Okay.</p> <p>7 Q. Do you -- do the DSM-5 criteria</p> <p>8 for ASD include anxiety?</p> <p>9 MS. HUNT: Object to form.</p> <p>10 And, Counsel, I'll let this go,</p> <p>11 but if we're going to go deep into the</p> <p>12 DSM criteria, I'd ask that he have a</p> <p>13 copy.</p> <p>14 MR. PADGETT: He discusses it</p> <p>15 in detail in his report.</p> <p>16 MS. HUNT: That's fine. But if</p> <p>17 you're asking him about a specific</p> <p>18 diagnostic criteria in detail, I'd ask</p> <p>19 that he have a copy. At this level,</p> <p>20 it's fine.</p> <p>21 THE WITNESS: I don't believe</p> <p>22 anxiety is a diagnostic criteria, but</p> <p>23 anxiety is a large component of</p> <p>24 autism.</p> <p>25</p>	<p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. Okay. So are you aware whether</p> <p>3 the only neurodevelopmental disorder that</p> <p>4 includes anxiety in its diagnostic criteria</p> <p>5 set forth in the DSM-5 is child --</p> <p>6 childhood-onset fluency disorder, also known</p> <p>7 as stuttering?</p> <p>8 MS. HUNT: Object to form.</p> <p>9 You can answer.</p> <p>10 THE WITNESS: That's outside of</p> <p>11 the purview of my mandate for this</p> <p>12 proceedings.</p> <p>13 QUESTIONS BY MR. PADGETT:</p> <p>14 Q. So you --</p> <p>15 A. I -- that's not something I</p> <p>16 have expertise in.</p> <p>17 Q. So you don't know; is that</p> <p>18 right?</p> <p>19 A. That's not -- that's not</p> <p>20 something that's part of my expertise, is</p> <p>21 that particular disorder, so...</p> <p>22 MS. HUNT: Counsel, if we're</p> <p>23 going to do a pop quiz on the DSM, I</p> <p>24 would ask that you bring a copy so we</p> <p>25 can look at it together.</p>

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<p style="text-align: right;">Page 70</p> <p>1 MR. PADGETT: He just said it 2 wasn't part of his purview. 3 QUESTIONS BY MR. PADGETT: 4 Q. But my question is, so you 5 don't -- my -- is, so you don't know whether 6 or not stuttering is the only 7 neurodevelopmental disorder that has anxiety 8 in the DSM-5 criteria? That's my question. 9 MS. HUNT: Object to form. 10 You can answer. 11 THE WITNESS: Yeah, again, I'm 12 not a clinician. I know a large 13 amount about anxiety and how to 14 measure it in animals. If you'd like 15 to ask me about that, I'd love to tell 16 you about that. 17 But this is -- the DSM -- this 18 is background information that was 19 intended to provide background and to 20 help the reader orient. 21 QUESTIONS BY MR. PADGETT: 22 Q. It's -- similar question. 23 As you sit here today, do you 24 know whether or not stuttering is the only 25 neurodevelopmental disorder that includes</p>	<p style="text-align: right;">Page 72</p> <p>1 You indicate there that the 2 open field and pup ultrasonic vocalizations 3 tests indicated elevated anxiety in male 4 offspring exposed to -- developmentally to 5 APAP. 6 First of all, with regard to 7 pup ultrasonic vocalizations, you're talking 8 about the change seen with regard to 9 decreased -- sorry, increased vocalizations, 10 right? 11 A. Yes. 12 Q. And with regard to -- was there 13 any -- I don't -- I didn't see it. Was there 14 anything in the study discussing that these 15 USVs, the ultrasonic vocalizations, were 16 unusual? 17 A. In this paper we discuss the 18 vocalizations in the sense that they're -- 19 there's sex differences in the presentation 20 of them and the fact that the pattern of them 21 are aberrant based on the prenatal exposure 22 to the medication. 23 Q. So they're increased, and how 24 were they aberrant? 25 A. So in that the males are</p>
<p style="text-align: right;">Page 71</p> <p>1 anxiety in its diagnostic criteria set forth 2 in the DSM-5? 3 MS. HUNT: Objection. Asked 4 and answered multiple times. 5 You can answer again. 6 THE WITNESS: That is not 7 something I know about, no. 8 MS. HUNT: Counsel, we've been 9 going a little over an hour. Is this 10 a good time for a break? 11 MR. PADGETT: Sure. 12 VIDEOGRAPHER: The time right 13 now is 9:48 a.m., and we're off the 14 record. 15 (Off the record at 9:48 a.m.) 16 VIDEOGRAPHER: The time right 17 now is 10:03 a.m., and we're back on 18 the record. 19 QUESTIONS BY MR. PADGETT: 20 Q. Back from a little break, 21 Dr. Pearson. Just a couple quick follow-up 22 questions on the Baker 2023 study. 23 If you could turn to page 11, 24 it's right before that last paragraph of the 25 article.</p>	<p style="text-align: right;">Page 73</p> <p>1 exhibiting more relative to the controls. 2 That exposed males are exhibiting more 3 vocalizations relative to the unexposed 4 males. 5 Q. So when you say "aberrant," 6 that's the same as more, or increased, right? 7 A. Increased or decreased would be 8 aberrant. 9 Q. Okay. And with regard to the 10 open field test, are you -- the only thing 11 that I saw statistically significant was the 12 decreased total ambulatory movement for the 13 males as reflected in Figure 2. 14 Is that right? 15 A. I'm going to Figure 2. 16 Q. At least following a Bonferroni 17 correction, right? 18 A. I'm sorry, could you say that 19 again? 20 Q. The only -- the only finding 21 that was statistically significant with 22 regard to the open field testing following 23 Bonferroni correction was the total 24 ambulatory movement as reflected in Figure 2 25 on page 4, correct?</p>

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<p>1 MS. HUNT: Object to the form 2 of the question. 3 You can answer. 4 THE WITNESS: That's not 5 correct. 6 So the ambulatory movements 7 were statistically different, the 8 rearings were different, and the 9 center durations were different based 10 on treatment. 11 QUESTIONS BY MR. PADGETT: 12 Q. My question was following 13 Bonferroni. 14 A. Bonferroni? 15 Q. Bonferroni. Correction. 16 The plus sign is for Bonferroni 17 correction statistical significance, and the 18 asterisk is following Bonferroni correction, 19 correct? 20 MS. HUNT: Object to the form 21 of the question. 22 You can answer. 23 THE WITNESS: That's not 24 entirely correct. So I believe you're 25 looking at Figure 2B?</p>	<p>1 animals, or increased rearings in the treated 2 animals, that would be consistent with the 3 ADHD model, correct? 4 MS. HUNT: Objection to form. 5 THE WITNESS: That is not 6 correct. Sorry. Apologies. That is 7 not correct. 8 We're not looking for 9 disturbances in these behavioral 10 paradigms. Directionality is not 11 required. We're looking for 12 perturbations in these behavioral 13 readouts. Increases in these 14 behaviors that are statistically 15 significant, decreases in these 16 behaviors that are statistically 17 significant can still be relevant for 18 ADHD-like behaviors. 19 We're not measuring ADHD in 20 these animals. They are animals, not 21 people. 22 QUESTIONS BY MR. PADGETT: 23 Q. And then with regard to 24 anxiety, do you see where it says, second, 25 the open -- after you discussed the open</p>
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<p>1 QUESTIONS BY MR. PADGETT: 2 Q. Yes. 3 A. That's for the sex stratified 4 analysis? 5 Q. Okay. Let me put it -- let me 6 ask it this way. 7 The open field test finding of 8 anxiety was based on the finding of decreased 9 total ambulation and decreased rearings in 10 the male mice as reflected in Figure 2, 11 correct? 12 A. That is the main finding in the 13 open field test, but the open field test is 14 not just measuring anxiety. In fact, that's 15 not the main finding of the open field. 16 That's locomotor -- locomotor behavior. 17 But you can also evaluate risk 18 assessment behavior, thigmotaxis behavior and 19 other behavioral paradigms, other behavioral 20 parameters, in the open field test. 21 Q. All right. And the main -- 22 when you say the main focus of the -- as it 23 relates to testing for ADHD, the main focus 24 of the open field test is that you're looking 25 for increased ambulation in the treated</p>	<p>1 field and USV tests, there was no effect in 2 the elevated plus maze, which is a common 3 assay for anxiety-related behavior, right? 4 A. You're on page 11? 5 Q. Yes. 6 MS. HUNT: Object to the form 7 of the question. 8 You can answer. 9 THE WITNESS: So if you're 10 asking me whether there were changes 11 in the elevated plus maze -- is that 12 your question? 13 QUESTIONS BY MR. PADGETT: 14 Q. Yes. 15 A. There were not changes in the 16 elevated plus maze. Statistically 17 significant changes in the elevated plus 18 maze. 19 Q. And as you state there, that -- 20 that is a common assay for anxiety-related 21 behavior, right? 22 A. It is a common rodent test for 23 anxiety-related behavior. 24 Q. So to the extent the conclusion 25 is that open field and pup ultrasonic were</p>

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<p>1 consistent with anxiety, the elevated plus 2 maze was not consistent with increased 3 anxiety -- 4 MS. HUNT: Object to the -- 5 QUESTIONS BY MR. PADGETT: 6 Q. -- correct? 7 MS. HUNT: Sorry. Object to 8 the form of the question. 9 You can answer. 10 THE WITNESS: As I stated 11 previously, the open field test that 12 was run with these mice, the main 13 intention of this test was to look at 14 local motor behavior. But the task 15 can also be used to look at mood and 16 anxiety-relevant behaviors as well. 17 Not mood. Anxiety-related behaviors 18 as well. Risk assessment-related 19 behaviors. 20 QUESTIONS BY MR. PADGETT: 21 Q. In your report, it looks like 22 pages 39 to 46, in the second half of that 23 section you discuss the ADHD model for -- 24 ADHD animal model, right? And various assays 25 used for it?</p>	<p>1 You can answer. 2 THE WITNESS: Are you asking me 3 whether I've amended that section 4 where I discuss the behavioral 5 paradigms? 6 QUESTIONS BY MR. PADGETT: 7 Q. Yes. 8 A. No, that's not been amended. 9 Q. Okay. 10 A. So the behavioral readouts that 11 have been provided here are examples of 12 behavioral paradigms. Any directionality of 13 discussion that's given here are provided as 14 examples. They're not provided as the only 15 types of readouts that are required to have 16 relevance for these behavioral readouts. 17 This is background information 18 that's provided as examples. This is not 19 meant to be comprehensive or the litmus test 20 for what's -- the only -- it's not 21 prescriptive as to what's required for the 22 outcomes for neurodevelopmental relevance. 23 Q. We discussed unpublished 24 research earlier, and there was some such 25 unpublished research that you indicated you</p>
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<p>1 A. In my -- in my report, I 2 discuss behavioral paradigms and outcome 3 variables that could be used to assess 4 outcomes that can be relevant for 5 neurodevelopmental outcomes such as ADHD and 6 ASD-relevant effects. 7 Q. And, you know, in terms of the 8 expected results consistent with the animal 9 model for ADHD, that increased ambulation and 10 increased rearings is what would be expected 11 for consistency with the ADHD animal model, 12 correct? 13 MS. HUNT: Object to form. 14 You can answer. 15 THE WITNESS: That is not in 16 line with the testimony that I've 17 given. 18 QUESTIONS BY MR. PADGETT: 19 Q. Okay. If that's what it says 20 in your report -- well, let me ask you this. 21 Have you -- you haven't amended 22 that section describing the animal model 23 assays for ASD and ADHD since your June 28 -- 24 sorry, June 21 amended report, right? 25 MS. HUNT: Object to form.</p>	<p>1 could not talk about because it was currently 2 in peer review. 3 Do you recall that discussion? 4 A. I recall that discussion. 5 Q. Okay. Are you relying on any 6 data or research that is currently in peer 7 review for your opinions in this case? 8 A. No. 9 Q. Do you anticipate providing a 10 supplemental report regarding that 11 unpublished research? 12 MS. HUNT: Objection. 13 You can answer. 14 THE WITNESS: As it states in 15 my report, I say that I'm open to any 16 new information that comes to light, 17 but my report is based solely on 18 published information -- published, 19 publicly accessible information in 20 forming my opinion and the weight of 21 evidence. 22 QUESTIONS BY MR. PADGETT: 23 Q. I mean, the unpublished data 24 that has been submitted for peer review, do 25 you have an anticipated date on when you will</p>

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<p>1 learn of whether it's been accepted for 2 publication? 3 MS. HUNT: Objection. 4 Answer, if you can. 5 THE WITNESS: I do not have -- 6 I can't refer to anything specifically 7 and answer that question. 8 QUESTIONS BY MR. PADGETT: 9 Q. Are you part of any peer review 10 group for any unpublished data or research 11 relating to a study on acetaminophen and 12 neurodevelopmental disorders? 13 MS. HUNT: Objection. 14 Answer, if you can. 15 THE WITNESS: I can't answer 16 that. 17 QUESTIONS BY MR. PADGETT: 18 Q. Not even whether you are? 19 A. It's -- it would not be proper 20 for me to answer that question. 21 Q. So when the unpublished 22 research was submitted for peer review, did 23 you disclose to whatever journal or journals 24 involved that you are doing -- you're being 25 paid by plaintiffs' counsel for this</p>	<p>1 that as per the rules of the journal. 2 QUESTIONS BY MR. PADGETT: 3 Q. Let's go outside anything 4 specific. 5 If you were to submit in six 6 months a study for -- a study article for 7 publication involving acetaminophen and 8 possible neurodevelopmental effects, would 9 you disclose to the journal that you're 10 submitting it to that you were being paid by 11 the plaintiffs' counsel in this case? 12 MS. HUNT: Object to the form 13 of the question. 14 You can answer. 15 THE WITNESS: I would not need 16 to disclose that because I do not 17 receive funding for my research. The 18 only things I would need to disclose 19 are my funding sources. So I'm not 20 conflicted. 21 Now, if somebody would like to 22 give me a research for my -- give me 23 funding for my research, then I would 24 disclose that. 25</p>
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<p>1 litigation? 2 MS. HUNT: Object to form. 3 You can answer. 4 THE WITNESS: So I'm just going 5 to go ahead and give some 6 clarification and go on the record by 7 saying I'm not indicating that I've 8 submitted anything, and I'm not 9 indicating that I'm peer reviewing 10 anything here. So we should just 11 dispense with any discussion of any of 12 this. 13 If I were peer reviewing 14 anything, I'm not -- by the rules of 15 the journal, I'm not allowed to 16 discuss that. So it would not be 17 proper for a continued discussion of 18 that. 19 And if I myself have data that 20 I'm submitting for publication, that's 21 the purview of my own research in my 22 own lab. 23 But again, if there's stuff 24 that's peer -- that I'm peer 25 reviewing, I'm not allowed to discuss</p>	<p>1 QUESTIONS BY MR. PADGETT: 2 Q. I think your report reflects 3 this, but did you look at documents produced 4 by the FDA in producing -- preparing your 5 report? 6 A. I did. 7 Q. Okay. And those documents are 8 as recent as 2022, right? 9 A. I do -- I do not recall the 10 recency of those documents, the date of the 11 recency of those documents, off the top of my 12 head. 13 Q. Okay. In any event, the 14 conclusion that the FDA has reached with 15 regard to any developmental neurotoxicity of 16 therapeutic doses of acetaminophen is not in 17 agreement with your opinions here, correct? 18 MS. HUNT: Objection. 19 Misstates evidence. 20 You can answer. 21 THE WITNESS: I've seen 22 opinions within FDA production that 23 individuals -- that the opinions are 24 mixed within the FDA, so I don't 25 necessarily agree with that statement.</p>

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<p style="text-align: right;">Page 86</p> <p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. Well, let me ask you this.</p> <p>3 The FDA has not come up -- come</p> <p>4 out with an FDA conclusion, publicly or</p> <p>5 privately, as far as you know, based on the</p> <p>6 documents reviewed, that are in agreement</p> <p>7 with your conclusions in this case, agree?</p> <p>8 MS. HUNT: Object to the form</p> <p>9 of the question.</p> <p>10 Answer, if you can.</p> <p>11 THE WITNESS: To my knowledge,</p> <p>12 the FDA hasn't seen my opinion, so how</p> <p>13 would they be able to opine on my</p> <p>14 conclusions?</p> <p>15 QUESTIONS BY MR. PADGETT:</p> <p>16 Q. I'm not asking whether they've</p> <p>17 seen it. I'm asking whether the FDA has come</p> <p>18 out, either publicly or privately, with a</p> <p>19 conclusion on behalf of the FDA that is</p> <p>20 consistent with your opinions in this case.</p> <p>21 MS. HUNT: Same objection.</p> <p>22 You can answer.</p> <p>23 THE WITNESS: My understanding</p> <p>24 is that the FDA is continuing to</p> <p>25 evaluate information as it comes.</p>	<p style="text-align: right;">Page 88</p> <p>1 THE WITNESS: Any safety</p> <p>2 committee regarding women's health? I</p> <p>3 do not believe I have.</p> <p>4 QUESTIONS BY MR. PADGETT:</p> <p>5 Q. As we're sitting here today,</p> <p>6 August 2023, the American College of</p> <p>7 Obstetricians and Gynecologists disagrees</p> <p>8 with your general causation opinion that</p> <p>9 acetaminophen is a developmental</p> <p>10 neurotoxicant capable of causing ASD,</p> <p>11 correct?</p> <p>12 A. My understanding is that the</p> <p>13 ACOG has released their statement that -- to</p> <p>14 that -- to that regard, yes. But I don't</p> <p>15 think that every single member of ACOG is</p> <p>16 necessarily in agreement with that.</p> <p>17 Q. And the same is true for the</p> <p>18 Society for Maternal-Fetal Medicine. As of</p> <p>19 today, the Society for Maternal-Fetal</p> <p>20 Medicine does not agree with your opinion --</p> <p>21 with your general causation opinion that</p> <p>22 acetaminophen is a developmental</p> <p>23 neurotoxicant capable of causing ASD,</p> <p>24 correct?</p> <p>25 MS. HUNT: Object to form.</p>
<p style="text-align: right;">Page 87</p> <p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. Have you seen any such FDA --</p> <p>3 any such conclusion on behalf of the FDA that</p> <p>4 is consistent with your opinions in this</p> <p>5 case?</p> <p>6 MS. HUNT: Object to the form</p> <p>7 of the question.</p> <p>8 You can answer.</p> <p>9 THE WITNESS: I haven't seen an</p> <p>10 opinion from the FDA that is in</p> <p>11 contradistinction to my opinion or</p> <p>12 supports my opinion.</p> <p>13 QUESTIONS BY MR. PADGETT:</p> <p>14 Q. Have you ever asked to serve on</p> <p>15 any decision-making committee regarding drug</p> <p>16 safety?</p> <p>17 Have you ever been asked to</p> <p>18 serve on any decision-making committee</p> <p>19 regarding drug safety?</p> <p>20 A. Not to my recollection, no.</p> <p>21 Q. Have you ever been asked to</p> <p>22 serve on any decision-making committee</p> <p>23 regarding women's health?</p> <p>24 MS. HUNT: Object to form.</p> <p>25 You can answer.</p>	<p style="text-align: right;">Page 89</p> <p>1 You can answer.</p> <p>2 THE WITNESS: Similar to the</p> <p>3 FDA, I don't think they've been able</p> <p>4 to see my report, but I've seen</p> <p>5 allusions to the -- to that regard,</p> <p>6 yes.</p> <p>7 QUESTIONS BY MR. PADGETT:</p> <p>8 Q. And same questions with regard</p> <p>9 to ACOG and Society for Maternal-Fetal</p> <p>10 Medicine.</p> <p>11 As of today, those</p> <p>12 organizations do not agree with you with</p> <p>13 regard to your general causation opinion that</p> <p>14 acetaminophen is a developmental</p> <p>15 neurotoxicant capable of causing ADHD,</p> <p>16 correct?</p> <p>17 MS. HUNT: Same objection.</p> <p>18 You can answer.</p> <p>19 THE WITNESS: I would give the</p> <p>20 same answer as before.</p> <p>21 QUESTIONS BY MR. PADGETT:</p> <p>22 Q. Okay. Are you aware of any</p> <p>23 medical organizations in the United States</p> <p>24 that as of today agree with your general</p> <p>25 causation opinion here?</p>

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<p style="text-align: right;">Page 90</p> <p>1 MS. HUNT: Object to form.</p> <p>2 You can answer.</p> <p>3 THE WITNESS: I haven't</p> <p>4 inventoried all the medical</p> <p>5 organizations to see what their</p> <p>6 opinions are with respect to this</p> <p>7 topic, so it would be difficult for me</p> <p>8 to answer that.</p> <p>9 QUESTIONS BY MR. PADGETT:</p> <p>10 Q. Well, I'm just asking you, as</p> <p>11 you sit here today, are you aware of any that</p> <p>12 agree with your general causation opinion in</p> <p>13 this case?</p> <p>14 MS. HUNT: Same objection.</p> <p>15 You can answer.</p> <p>16 THE WITNESS: And I understand</p> <p>17 from the Bauer consensus statement</p> <p>18 that there's a lot of individuals that</p> <p>19 are medical practitioners that have a</p> <p>20 similar viewpoint.</p> <p>21 QUESTIONS BY MR. PADGETT:</p> <p>22 Q. Are the signers of the Bauer</p> <p>23 2021 consensus statement a medical</p> <p>24 organization collectively?</p> <p>25 A. I don't know.</p>	<p style="text-align: right;">Page 92</p> <p>1 identification.)</p> <p>2 QUESTIONS BY MR. PADGETT:</p> <p>3 Q. Okay. I'm going to hand you</p> <p>4 what's been marked as Exhibit 70.</p> <p>5 Can you identify this</p> <p>6 Exhibit 70 for me?</p> <p>7 A. Yes, this is a -- this is an</p> <p>8 e-mail chain.</p> <p>9 Q. And there's an e-mail -- and</p> <p>10 one of them -- this e-mail is from you, at</p> <p>11 least the December 18, 2022, 11:21 a.m.</p> <p>12 There's an e-mail from you to fellow</p> <p>13 coauthors on the Baker 2023 study, right?</p> <p>14 A. Yes.</p> <p>15 Q. And it's Dr. Brennan -- sorry.</p> <p>16 Dr. Baker, Dr. Hamblin and Dr. Yang, right?</p> <p>17 A. Yes.</p> <p>18 Q. And there you note that Baker</p> <p>19 2023 has been accepted for publication,</p> <p>20 correct?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. And then you state,</p> <p>23 quote, "We are pissing off Johnson & Johnson</p> <p>24 and all obstetricians simultaneously. I'd</p> <p>25 say that's impactful," period, end quote.</p>
<p style="text-align: right;">Page 91</p> <p>1 Q. Do you have a draft of an</p> <p>2 additional expert report that you're working</p> <p>3 on now, or anything like that?</p> <p>4 MS. HUNT: Object to the form</p> <p>5 of the question.</p> <p>6 Answer, if you can.</p> <p>7 THE WITNESS: I don't believe I</p> <p>8 have another draft of an expert</p> <p>9 report.</p> <p>10 QUESTIONS BY MR. PADGETT:</p> <p>11 Q. Okay. So as of today, we have</p> <p>12 in writing whatever your opinions are in this</p> <p>13 case, correct?</p> <p>14 MS. HUNT: Object to form.</p> <p>15 You can answer.</p> <p>16 THE WITNESS: My opinion -- my</p> <p>17 expert report is subject to change</p> <p>18 based on new information, as it says</p> <p>19 in my expert report.</p> <p>20 QUESTIONS BY MR. PADGETT:</p> <p>21 Q. But as of today, your opinions</p> <p>22 are set forth in your expert report --</p> <p>23 reports, plural?</p> <p>24 A. That is a fair statement.</p> <p>25 (Pearson Exhibit 70 marked for</p>	<p style="text-align: right;">Page 93</p> <p>1 Correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. At this time, you had</p> <p>4 been engaged by plaintiffs' counsel -- strike</p> <p>5 that.</p> <p>6 At this time, you had at least</p> <p>7 been contacted by plaintiffs' counsel for</p> <p>8 this litigation nine months earlier, based on</p> <p>9 your prior testimony?</p> <p>10 A. That sounds about right.</p> <p>11 Q. Okay. Was one of your research</p> <p>12 team's goals in conducting this study to make</p> <p>13 an impact by, quote, pissing off, end quote,</p> <p>14 Johnson & Johnson?</p> <p>15 A. No, that would not have been</p> <p>16 the goal.</p> <p>17 Q. Why did you say this then as to</p> <p>18 Johnson & Johnson specifically?</p> <p>19 A. Well, this statement just</p> <p>20 reflects the sort of frustration at sort of</p> <p>21 the inaction and controversy and skepticism</p> <p>22 about the preclinical literature and the</p> <p>23 observational epi literature, and the fact</p> <p>24 that many of us scientists have been working</p> <p>25 on this topic, and the fact that there's just</p>

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<p>1 inaction and continued skepticism.</p> <p>2 And so working on this and</p> <p>3 working on this, and the fact that we talk</p> <p>4 about this topic and it's met with disdain or</p> <p>5 met with, again, to use the same term over</p> <p>6 and over again, skepticism, finally getting</p> <p>7 this paper accepted elicited this response,</p> <p>8 which was a bit tongue in cheek.</p> <p>9 Q. And as we -- strike that.</p> <p>10 And was one of your research</p> <p>11 team's goals in conducting the study to make</p> <p>12 an impact by, quote, "pissing off...all</p> <p>13 obstetricians," end quote?</p> <p>14 A. No.</p> <p>15 Q. Did you or any others on your</p> <p>16 research team follow up to see the extent</p> <p>17 of it -- of any impact paid by pissing off</p> <p>18 Johnson & Johnson?</p> <p>19 A. We did not follow up on that,</p> <p>20 no.</p> <p>21 Q. Did you or any your research</p> <p>22 team follow up to see the extent of any</p> <p>23 impact made by, quote, "pissing off," end</p> <p>24 quote, all obstetricians?</p> <p>25 A. No.</p>	<p>1 Dr. Pearson, you can answer.</p> <p>2 THE WITNESS: If you're asking</p> <p>3 me whether I think the impact of the</p> <p>4 study is that it frustrates the</p> <p>5 corporate entity and it frustrates</p> <p>6 clinicians, that's not what we believe</p> <p>7 the impact of the study actually is.</p> <p>8 We believe the impact of the</p> <p>9 study is by providing more and strong</p> <p>10 evidence that the medication is a</p> <p>11 neurodevelopmental toxicant that can</p> <p>12 contribute to these health outcomes.</p> <p>13 We think that it does challenge</p> <p>14 this view that the corporate entity</p> <p>15 and the clinicians have, and that is</p> <p>16 important to us.</p> <p>17 QUESTIONS BY MR. PADGETT:</p> <p>18 Q. Do you believe it's</p> <p>19 inappropriate for an OB/GYN or a</p> <p>20 maternal-fetal medicine physician to consider</p> <p>21 treatment of fever and pain in pregnant women</p> <p>22 an important issue?</p> <p>23 MS. HUNT: Object to the form</p> <p>24 of the question.</p> <p>25 You can answer.</p>
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<p>1 Q. Why did you find it impactful</p> <p>2 to piss off all obstetricians?</p> <p>3 MS. HUNT: Object to the form</p> <p>4 of the question.</p> <p>5 You can answer.</p> <p>6 THE WITNESS: Can you restate</p> <p>7 that question? I'm sorry.</p> <p>8 QUESTIONS BY MR. PADGETT:</p> <p>9 Q. Why did you find it impactful</p> <p>10 to piss off all obstetricians, as you put it</p> <p>11 here?</p> <p>12 A. We didn't. Again, as I said,</p> <p>13 this -- this statement just reflected our</p> <p>14 excitement about finally getting our paper</p> <p>15 published and being able to provide more</p> <p>16 support for what we believe to be an</p> <p>17 important topic.</p> <p>18 Q. So are you now retracting that</p> <p>19 you'd say that this study was impactful?</p> <p>20 MS. HUNT: Object to --</p> <p>21 QUESTIONS BY MR. PADGETT:</p> <p>22 Q. In pissing off J&J and all</p> <p>23 obstetricians simultaneously?</p> <p>24 MS. HUNT: Object to the form</p> <p>25 of the question. Misstates testimony.</p>	<p>1 THE WITNESS: Can you repeat</p> <p>2 the question?</p> <p>3 QUESTIONS BY MR. PADGETT:</p> <p>4 Q. Do you believe it's</p> <p>5 inappropriate for an OB/GYN or a physician or</p> <p>6 a maternal-fetal medicine physician to</p> <p>7 consider treatment of fever and/or pain in</p> <p>8 pregnant women an important issue?</p> <p>9 MS. HUNT: Same objection.</p> <p>10 You can answer.</p> <p>11 THE WITNESS: I do -- I do not</p> <p>12 think that a maternal-fetal medicine</p> <p>13 doctor or obstetrician should not</p> <p>14 consider that an important issue.</p> <p>15 They should consider that an important</p> <p>16 issue.</p> <p>17 I would never argue the</p> <p>18 alternative.</p> <p>19 QUESTIONS BY MR. PADGETT:</p> <p>20 Q. And if you want to refer to</p> <p>21 your report, you can.</p> <p>22 In your summary of the study on</p> <p>23 page 113 of your report, you note that a</p> <p>24 single dose of 150 milligram per kilogram per</p> <p>25 day was used, and you state that was at the</p>

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<p>1 high end of dosing, correct?</p> <p>2 A. You say on 113 on the report?</p> <p>3 Q. Yes.</p> <p>4 MS. HUNT: I'm sorry, can you</p> <p>5 specify the study we're talking about?</p> <p>6 MR. PADGETT: We're talking --</p> <p>7 sorry. We're talking about Baker</p> <p>8 2023.</p> <p>9 MS. HUNT: Thank you.</p> <p>10 THE WITNESS: Which paragraph?</p> <p>11 QUESTIONS BY MR. PADGETT:</p> <p>12 Q. Strike that.</p> <p>13 If you could turn to Baker</p> <p>14 2023, it's exhibit...</p> <p>15 Which exhibit is that?</p> <p>16 Apologies.</p> <p>17 A. 68.</p> <p>18 Q. 68.</p> <p>19 Turn to page 2, please.</p> <p>20 A. (Witness complies.)</p> <p>21 Q. And there on the right</p> <p>22 common -- or column, you state that "the dose</p> <p>23 of 150 milligrams per kilogram per day is</p> <p>24 within the range of human exposure accounting</p> <p>25 for allometric scaling and has previously</p>	<p>1 MS. HUNT: Objection.</p> <p>2 QUESTIONS BY MR. PADGETT:</p> <p>3 Q. With acetaminophen.</p> <p>4 MS. HUNT: Object to the form</p> <p>5 of the question.</p> <p>6 You can answer.</p> <p>7 THE WITNESS: There's -- that's</p> <p>8 a massive literature, so you might</p> <p>9 have to narrow a bit.</p> <p>10 QUESTIONS BY MR. PADGETT:</p> <p>11 Q. Has a 150 milligrams per</p> <p>12 kilogram dose been shown to cause liver</p> <p>13 toxicity in mice?</p> <p>14 MS. HUNT: Object to the form</p> <p>15 of the question.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: It would depend</p> <p>18 on your definition of liver toxicity.</p> <p>19 If your measure is AS -- an AST</p> <p>20 elevation, an ALT elevation, liver</p> <p>21 necrosis, liver failure -- I mean, if</p> <p>22 you're referring to a specific study,</p> <p>23 I'd be happy to look at it.</p> <p>24 But generally 100 milligrams</p> <p>25 per kilogram does not cause liver</p>
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<p>1 been shown to result in the highest serum</p> <p>2 concentrations of APAP without inducing liver</p> <p>3 toxicity in mice."</p> <p>4 Correct?</p> <p>5 A. That's what it states.</p> <p>6 Q. Okay. Sorry. Can you turn</p> <p>7 back to page 113 of your report?</p> <p>8 A. I'm there.</p> <p>9 Q. Yeah.</p> <p>10 Right after -- it's about the</p> <p>11 fourth or fifth sentence there in your</p> <p>12 summary for Baker 2023. You state that you</p> <p>13 opted to be at the high end of dosing to see</p> <p>14 if an effect existed, right?</p> <p>15 A. That's what it states.</p> <p>16 Q. Okay. And so this is --</p> <p>17 150 milligrams per kilogram per day is not</p> <p>18 just at the high end of dosing, but Baker</p> <p>19 2023 confirms that doses above 100 milligrams</p> <p>20 per kilogram per day can induce liver</p> <p>21 toxicity, right?</p> <p>22 A. Baker, et al., does not say</p> <p>23 that.</p> <p>24 Q. At what levels have liver</p> <p>25 toxicity been shown in mice?</p>	<p>1 toxicity in mice.</p> <p>2 QUESTIONS BY MR. PADGETT:</p> <p>3 Q. But 150 milligrams per</p> <p>4 kilogram?</p> <p>5 A. Generally, no.</p> <p>6 Q. Okay. Has 150 milligrams per</p> <p>7 kilogram been shown in published literature</p> <p>8 to show liver toxicity in mice?</p> <p>9 A. I would repeat my response from</p> <p>10 before. It depends on your definition of</p> <p>11 liver toxicity.</p> <p>12 Q. Did you review Dr. Cabrera's</p> <p>13 report in this case?</p> <p>14 A. I did.</p> <p>15 Q. It was previously marked as</p> <p>16 Exhibit 12 in this litigation. I'll hand it</p> <p>17 to you, if you want to have it handy.</p> <p>18 But I'm referring to page 34.</p> <p>19 MS. HUNT: Do you have an extra</p> <p>20 copy, Counsel?</p> <p>21 MR. PADGETT: Oh --</p> <p>22 MS. KAPKE: We don't. I'm</p> <p>23 sorry.</p> <p>24 MR. PADGETT: We don't. I'm</p> <p>25 sorry.</p>

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<p>1 MS. KAPKE: It's the Cabrera 2 report. 3 MS. HUNT: Okay. In the 4 future, I'd just -- 5 MR. PADGETT: Yeah. 6 MS. HUNT: -- ask for the 7 courtesy of having a copy for me, 8 please. 9 QUESTIONS BY MR. PADGETT: 10 Q. Dr. Cabrera put the mouse 11 single therapeutic dose, and it's in bold on 12 page 34 there, at 150 to 200 milligrams per 13 kilogram, as reported from experimental 14 studies and calculated using human equivalent 15 conversions, right? 16 A. In bold it states, "Based on 17 these data and calculations, a mouse dose of 18 approximately 150 to 200 milligrams per 19 kilogram." And then it goes on. 20 Q. Would be in the therapeutic -- 21 A. In the therapeutic range. 22 Q. Okay. And he also states that 23 a rat single therapeutic dose would be at 100 24 to 150 milligrams per kilogram, as reported 25 from experimental studies and calculated</p>	<p>1 THE WITNESS: No, I think 2 that's a -- I don't think you can 3 narrow it to a single point like that. 4 It depends on the study. It depends 5 on the route of administration. It 6 depends on the application. It 7 depends on if you're looking for fever 8 reduction. It depends on if you're 9 looking for pain. It depends on if 10 you're doing toxicity. Amongst other 11 things. 12 QUESTIONS BY MR. PADGETT: 13 Q. And I'm talking about the human 14 equivalent therapeutic dose in mice. 15 Would you a -- as in per the 16 label, would you agree that it is somewhere 17 below 150 milligrams per kilogram for a 18 single dose? 19 MS. HUNT: Objection. Form. 20 Dr. Pearson, you can answer. 21 THE WITNESS: Well, this is 22 Dr. Cabrera's report. Dr. Cabrera is 23 saying it's between 100 -- 24 approximately 150 to 200 milligrams 25 per kilogram.</p>
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<p>1 using AGD conversions, correct? 2 A. That's what I read. 3 Q. Okay. So the human -- do you 4 agree that human equivalent therapeutic dose 5 in mice is there's -- is therefore somewhere 6 below 150 milligrams per kilogram per day? 7 MS. HUNT: Object to form. 8 You can answer. 9 THE WITNESS: You're asking 10 whether I think it's below this? 11 QUESTIONS BY MR. PADGETT: 12 Q. Below 150 milligrams per 13 kilograms per day for mice. 14 A. I don't -- 15 MS. HUNT: Same objection. 16 THE WITNESS: -- necessarily 17 agree with that, no. 18 QUESTIONS BY MR. PADGETT: 19 Q. Strike that. Strike that. 20 Would you agree that the human 21 equivalent single therapeutic dose in mice is 22 somewhere below 150 milligrams per kilogram? 23 MS. HUNT: Object to the form 24 of the question. 25 Answer, if you understand it.</p>	<p>1 I don't have any strong reason 2 to disagree with Dr. Cabrera. 3 QUESTIONS BY MR. PADGETT: 4 Q. Okay. 5 A. So in that sense, I would not 6 agree with you. 7 Q. Would you agree that a human 8 equivalent therapeutic dose in mice, using 9 Dr. Cabrera's numbers, would be below 10 200 milligrams per kilogram for a single 11 dose? 12 MS. HUNT: Object to the form 13 of the question. 14 You can answer. 15 THE WITNESS: I would concur 16 with Dr. Cabrera, which is 17 approximately 150 to 200 milligrams 18 per kilogram as a human equivalent 19 dose, as stated in his report. 20 QUESTIONS BY MR. PADGETT: 21 Q. Therapeutic dose, right? 22 MS. HUNT: Object to form. 23 You can answer. 24 THE WITNESS: No. He's saying 25 is therapeutic, not therapeutic dose.</p>

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<p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. Okay.</p> <p>3 A. He's saying what is</p> <p>4 therapeutic. He's not saying a therapeutic</p> <p>5 dose.</p> <p>6 Q. Did you exclude --</p> <p>7 A. There's a difference.</p> <p>8 Q. Sorry.</p> <p>9 Did you exclude studies from</p> <p>10 your report that administer a dose above</p> <p>11 200 milligrams per kilogram in mice or rats?</p> <p>12 MS. HUNT: Object to form.</p> <p>13 QUESTIONS BY MR. PADGETT:</p> <p>14 Q. In your weight of evidence</p> <p>15 analysis.</p> <p>16 A. In my weight of evidence</p> <p>17 analysis, I certainly excluded studies that</p> <p>18 were not just above 200, but well above 200 I</p> <p>19 excluded.</p> <p>20 Q. Beck -- the Beck study was</p> <p>21 including your weight of analysis, correct?</p> <p>22 A. I included that, yes.</p> <p>23 Q. Okay. And that was -- that</p> <p>24 involved doses at 250 milligrams per kilogram</p> <p>25 and 500 milligrams per kilogram, correct?</p>	<p>1 it was -- included a dose of 350 milligrams</p> <p>2 per kilogram single dose, right?</p> <p>3 A. I included Rigobello.</p> <p>4 Q. Okay. Are your opinions in</p> <p>5 this case not limited to answering the</p> <p>6 question of whether exposure to therapeutic</p> <p>7 doses in humans of acetaminophen in utero can</p> <p>8 cause ASD or ADHD?</p> <p>9 A. The specific language I used in</p> <p>10 my report was whether reasonable doses of</p> <p>11 acetaminophen contribute to</p> <p>12 neurodevelopmental disorders such as ASD-like</p> <p>13 and ADHD-like outcomes in rodent models and</p> <p>14 in vitro models.</p> <p>15 Q. Can you turn to page 4 of your</p> <p>16 report?</p> <p>17 A. (Witness complies.)</p> <p>18 Q. Under mandate there --</p> <p>19 A. Yes.</p> <p>20 Q. -- you state, quote, "My expert</p> <p>21 report addresses whether there is a</p> <p>22 biologically plausible explanation for the</p> <p>23 increased risk of neurodevelopmental</p> <p>24 disorders ASD and ADHD in offspring with</p> <p>25 prenatal use of APAP, and whether the</p>
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<p>1 A. It was, I believe, zero, 250</p> <p>2 and 500, if I remember correctly. I can</p> <p>3 look.</p> <p>4 Q. And --</p> <p>5 A. 125 as well.</p> <p>6 Q. But it did include 250 and</p> <p>7 500 milligrams per kilogram single dose?</p> <p>8 A. Zero, 125, 250, 500.</p> <p>9 Q. Okay. And Rigobello, among its</p> <p>10 dosing -- doses included 350 milligrams per</p> <p>11 kilogram, correct?</p> <p>12 A. I would have to look.</p> <p>13 Q. Sure. It's in your...</p> <p>14 A. Rigobello was mouse.</p> <p>15 Q. You have a chart on mouse --</p> <p>16 mice.</p> <p>17 A. Yeah, I'm looking for that</p> <p>18 right now.</p> <p>19 Q. Rigobello was rat.</p> <p>20 A. Rigobello was rat?</p> <p>21 Q. Yes. Page 83 of your report.</p> <p>22 A. Yeah, so that was zero, 35 and</p> <p>23 350.</p> <p>24 Q. So you included Rigobello in</p> <p>25 your weight of evidence analysis even though</p>	<p>1 preclinical literature supports that</p> <p>2 therapeutic, clinical and translationally</p> <p>3 relevant preclinical doses of APAP show</p> <p>4 evidence of harm to the central nervous</p> <p>5 system, particularly to the developing</p> <p>6 mammalian brain."</p> <p>7 Did I read that right?</p> <p>8 A. Yeah. And in parentheses,</p> <p>9 "They were translationally relevant."</p> <p>10 "What is translationally</p> <p>11 relevant are rodent doses that are well below</p> <p>12 those causing acute liver failure, and</p> <p>13 particularly the doses that are analgesic or</p> <p>14 antipyretic in that species and lower."</p> <p>15 Q. So regardless of whether it was</p> <p>16 equivalent of a therapeutic human dose, if it</p> <p>17 was below doses causing acute liver failure</p> <p>18 in a rodent, you included it?</p> <p>19 MS. HUNT: Object to the form</p> <p>20 of the question.</p> <p>21 You can answer.</p> <p>22 THE WITNESS: And it states</p> <p>23 here it's translationally relevant.</p> <p>24 QUESTIONS BY MR. PADGETT:</p> <p>25 Q. If you could turn to page 2,</p>

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<p style="text-align: right;">Page 110</p> <p>1 left column, middle of the first column of 2 Baker 2023. 3 A. Middle of the left column? 4 Q. Yes. 5 A. Okay. 6 Q. It states -- do you see the 7 sentence that starts "Finally"? About the 8 middle of the first full paragraph. 9 A. Middle of the first full 10 paragraph. I'm having trouble finding that. 11 MS. HUNT: I am, too. 12 QUESTIONS BY MR. PADGETT: 13 Q. Page 2, left column, first 14 paragraph, middle of that paragraph. It 15 starts with "Finally, the mechanisms." 16 A. Is it -- can you tell me... 17 Q. It's right before Philippot 18 2018. 19 MS. HUNT: Oh. 20 THE WITNESS: Oh, I see it. 21 QUESTIONS BY MR. PADGETT: 22 Q. Okay. 23 A. I've got it. "Finally, the 24 mechanisms linking." Okay. 25 Q. There you state, quote,</p>	<p style="text-align: right;">Page 112</p> <p>1 biomarker studies. 2 Q. I'm talking since publication 3 of Baker 2023. 4 A. Klein, Xie, that's stuff 5 that -- 6 Q. Okay. 7 A. -- that -- the rate that the 8 studies are coming out, it's compounding. 9 Q. And Klein 2023 included dosing 10 at 350 milligrams per kilogram -- 11 A. Yes. 12 Q. -- which is more than twice the 13 high end of the dosing referred to in Baker 14 2023 of 150 milligrams per kilogram, correct? 15 MS. HUNT: Object to the form 16 of the question, as it relates to the 17 wrong species. 18 You can answer. 19 MR. PADGETT: Object to form 20 only. 21 MS. HUNT: Okay. 22 THE WITNESS: So 350 milligrams 23 per kilogram can be appropriate if you 24 apply allometric scaling. 25 Rodents are not humans. Rats</p>
<p style="text-align: right;">Page 111</p> <p>1 "Finally, the mechanisms linking APAP 2 exposure to abnormal neurodevelopment are 3 unclear," period, end quote. 4 Do you still agree with that 5 statement? 6 A. In part. But what the 7 statement is indicating is that we don't know 8 everything. Just because we don't know 9 everything doesn't mean we know anything. 10 So when we write in science, 11 when we're writing a grant proposal, when 12 we're writing a paper, we have to be very 13 conservative in how we write. We have to say 14 that, you know, we don't know everything, 15 therefore, we need to learn more. And that's 16 almost always the case. 17 Q. What studies have been 18 published this year that now make clear -- 19 that now make the mechanism linking APAP 20 exposure to abnormal neurodevelopment, quote, 21 clear, end quote? 22 A. A lot of the studies are making 23 things clearer. In 2021, 2022, 2023, there's 24 a lot that's been published. In vitro 25 studies, in vivo studies, more epi, more</p>	<p style="text-align: right;">Page 113</p> <p>1 and mice have heartbeats that are 500 2 times -- 500 beats per minute. They 3 consume oxygen at rates that are much, 4 much higher than humans. 5 You can't do direct dosing 6 conversions between rodents and 7 humans. That's not appropriate. 8 QUESTIONS BY MR. PADGETT: 9 Q. But that's 150 milligrams per 10 kilogram higher than the high end of 11 Dr. Cabrera's therapeutic dose range of 150 12 to 200 milligrams per kilograms for a single 13 dose, right? 14 MS. HUNT: Same objection. 15 You can answer. 16 THE WITNESS: The Klein, et 17 al., study used allometric scaling in 18 their dose justification as well. 19 There's various approaches to 20 allometric scaling. There's not 21 one -- there's not a single allometric 22 scaling approach. 23 QUESTIONS BY MR. PADGETT: 24 Q. It's 150 milligrams per 25 kilograms higher, though, than the range</p>

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<p>1 provided by Dr. Cabrera for rats for 2 therapeutic allometric dosing per a single 3 dose pursuant to his HE -- human equivalent 4 dose analysis. Agree? 5 A. The -- 6 MS. HUNT: Objection. Form. 7 You can answer. 8 THE WITNESS: Klein and 9 colleagues aren't relying on 10 Dr. Cabrera's expertise in deciding on 11 their dosing. They get to decide that 12 on their own. 13 QUESTIONS BY MR. PADGETT: 14 Q. You reference -- you discuss in 15 Baker 2023 the upregulation of estrogen 16 response in females. This is on page 7, 17 bottom right. 18 Did you or your team do any 19 analysis to determine if these changes seen 20 were adverse or adaptive? 21 A. If they were adverse or 22 adaptive. We did not have the funding to 23 follow up on those pathways. 24 Q. Did you do any analysis to 25 determine if these changes were transient or</p>	<p>1 MS. HUNT: Objection. 2 Misstates evidence. 3 You can answer. 4 THE WITNESS: The exposure of 5 the study, acetaminophen prenatal and 6 the epidemiology discussion, is 7 focused on neurodevelopmental impacts 8 of prenatal acetaminophen on ADHD. 9 ASD is discussed in the introduction 10 as well. 11 But the outcomes are discussed 12 more agnostically for disease, and we 13 do that intentionally because 14 neurodevelopmental disorders are 15 highly comorbid with each other. We 16 intentionally don't try to pin results 17 so tightly to one diagnostic outcome 18 for multiple reasons. 19 One, because of these 20 transdiagnostic effects. Also, the 21 outcomes we found weren't so 22 ASD-specific -- or, sorry, 23 ADHD-specific. 24 Also, we are dealing with 25 rodents. You know, rodents aren't</p>
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<p>1 permanent? 2 A. We know these effects are not 3 transient because these effects were seen 4 after the dosing had ceased. 5 Q. Does your -- does Baker 2023 6 describe how these findings would be 7 associated specifically with ASD? 8 A. Are you asking me how these 9 effects are associated with ASD? 10 Q. No. 11 Does Baker -- the Baker 2023 12 article describe how these findings would be 13 associated with ASD? 14 A. The Baker 2023 paper does not 15 focus on ASD specifically. 16 Q. Does Baker -- the Baker 2023 17 article describe how these findings would be 18 associated with ADHD? 19 A. The relevance of these findings 20 to ADHD is discussed. The potential 21 relevance of these findings to ADHD is 22 discussed. 23 Q. And that's the anxiety 24 discussed -- issues discussed in the 25 conclusion?</p>	<p>1 little humans, as I've stated. 2 ADHD-like outcomes in rodents aren't 3 easy to model. It takes strong 4 expertise to be able to do this work. 5 We're very equipped to do that work. 6 So in our results, we talk 7 about our results as we find them and 8 are very conservative about how we do 9 that. 10 Our RNA sequencing results we 11 talk about in terms of pathways and 12 avoid trying to overattribute these 13 pathways to ASD and ADHD influences. 14 QUESTIONS BY MR. PADGETT: 15 Q. If you turn to the conclusion 16 of Baker 2023 on page 11. 17 You state there -- there's a 18 sentence that starts "It." 19 A. "It is also possible"? 20 Q. Yeah. 21 Quote, "It is also possible 22 that ADHD is too complex a human disorder to 23 be translated into human behavior," end 24 quote. 25 As you sit here today, do you</p>

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<p>1 agree with that statement in Baker 2023?</p> <p>2 A. What is -- what is attempting</p> <p>3 to be communicated here is that you may not</p> <p>4 be able to capture the full -- the full</p> <p>5 entity that is human ADHD in a single animal</p> <p>6 model. You have to compartmentalize it into</p> <p>7 symptoms and symptom domains. So essentially</p> <p>8 the idea that you can look for every aspect</p> <p>9 of ADHD in one animal model might be</p> <p>10 overambitious.</p> <p>11 Q. Is it your opinion that the</p> <p>12 full range of ADHD in humans is captured by</p> <p>13 the entirety of the animal models for ADHD?</p> <p>14 MS. HUNT: Object to the form</p> <p>15 of the question.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: I believe that's</p> <p>18 outside of the scope of my mandate for</p> <p>19 this proceeding.</p> <p>20 QUESTIONS BY MR. PADGETT:</p> <p>21 Q. I'm -- no, I think -- I think</p> <p>22 it's very within your expert report, and it's</p> <p>23 relevant to this quote, this line, from Baker</p> <p>24 2023.</p> <p>25 My question is, is it your</p>	<p>1 MS. HUNT: Object to form.</p> <p>2 You can answer.</p> <p>3 THE WITNESS: Rats and mice do</p> <p>4 not have a spoken language that is as</p> <p>5 complex as humans do, but they do have</p> <p>6 vocal communication, and they do have</p> <p>7 a rich vocal repertoire that can be</p> <p>8 measured.</p> <p>9 QUESTIONS BY MR. PADGETT:</p> <p>10 Q. Are you consulting on any</p> <p>11 litigated matters currently besides this</p> <p>12 case?</p> <p>13 A. No.</p> <p>14 Q. Have you ever been involved in</p> <p>15 any other litigation involving acetaminophen</p> <p>16 exposure?</p> <p>17 A. No.</p> <p>18 Q. Have you ever been involved in</p> <p>19 any litigation involving ASD or ADHD?</p> <p>20 A. I have not.</p> <p>21 Q. Have you ever been involved in</p> <p>22 other litigation involving exposure to</p> <p>23 medication or chemicals and allegations of</p> <p>24 adverse health effects?</p> <p>25 A. I have not.</p>
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<p>1 opinion that the animal models for ADHD</p> <p>2 collectively --</p> <p>3 A. Okay. I understand.</p> <p>4 Q. -- capture the full range of</p> <p>5 ADHD behaviors in humans?</p> <p>6 A. Yes. That's a good question.</p> <p>7 So I believe the animal models</p> <p>8 can capture the full range of the behavior --</p> <p>9 behavioral sequelae that are exhibited in</p> <p>10 humans that are living with ADHD.</p> <p>11 Q. Animals cannot?</p> <p>12 A. Animals can.</p> <p>13 Q. Animals -- I'm sorry. Animals</p> <p>14 cannot talk, correct?</p> <p>15 A. Animals can communicate.</p> <p>16 Q. Animals cannot -- do you agree</p> <p>17 that animals cannot talk like humans?</p> <p>18 MS. HUNT: Object to form.</p> <p>19 You can -- you can answer.</p> <p>20 THE WITNESS: Animals can</p> <p>21 communicate with vocal communication.</p> <p>22 QUESTIONS BY MR. PADGETT:</p> <p>23 Q. Dr. Baker {sic}, my question</p> <p>24 is, can rats or mice communicate in the</p> <p>25 expressive language that humans can?</p>	<p>1 Q. Dr. Pearson, are you relying on</p> <p>2 any other expert reports for your opinions in</p> <p>3 this case?</p> <p>4 A. I relied on Dr. Cabrera,</p> <p>5 Dr. Louie, Dr. Baccarelli, and Dr. Hollander.</p> <p>6 Sorry. I reviewed</p> <p>7 Dr. Hollander; I didn't rely upon it.</p> <p>8 Q. And to be clear, I'm asking if</p> <p>9 you relied on these other named experts. You</p> <p>10 already clarified you're not relying on</p> <p>11 Dr. Hollander.</p> <p>12 Have you relied on</p> <p>13 Dr. Baccarelli, Dr. Cabrera and Dr. Louie for</p> <p>14 your opinions in this case?</p> <p>15 MS. HUNT: Object to form.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: I cite all of</p> <p>18 these reports that I just listed to</p> <p>19 you in my report and defer to them on</p> <p>20 a lot of their expertise. Their</p> <p>21 expert reports don't change my expert</p> <p>22 report.</p> <p>23 So I drafted my full expert</p> <p>24 report before I reviewed theirs, and</p> <p>25 having reviewed their expert reports,</p>

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<p>1 it did not substantially change my 2 expert report. 3 QUESTIONS BY MR. PADGETT: 4 Q. You said did not? 5 A. It did not change my expert 6 report. So having reviewed theirs, I did not 7 need to modify mine. 8 Q. At page 3 of your expert 9 report, you describe, beginning of your 10 discussion, a weight of evidence methodology 11 that you reviewed published preclinical 12 studies evaluating the effects of gestational 13 and perinatal APAP exposure on 14 neurodevelopmental disorders. 15 And you are not limiting your 16 evaluation to ASD or ADHD specifically, 17 correct? 18 MS. HUNT: Object to form. 19 You can answer. 20 THE WITNESS: It's difficult 21 for me to answer your question. 22 Can you -- can you elaborate a 23 bit? 24 QUESTIONS BY MR. PADGETT: 25 Q. In your evaluation of this</p>	<p>1 MS. HUNT: Object to form. 2 You can answer. 3 THE WITNESS: So it's -- I 4 believe it states clearly in my report 5 where that catchment was, but without 6 looking super clearly, I believe it 7 was either postnatal day 14 or 15? 8 Yeah. 9 QUESTIONS BY MR. PADGETT: 10 Q. Was it PN -- is it postnatal 11 day 10 or postnatal day 14? 12 A. Before I say for certain, I 13 would need to find it. 14 But the first -- the first one 15 or two weeks postnatal are equivalent to the 16 third trimester in human brain development. 17 Q. Okay. 18 A. So that's the justification to 19 include that as the -- in the exposure -- 20 exposure window, to include the human 21 prenatal equivalent. 22 Q. And did you include studies 23 in -- animal studies in your weight of 24 analysis evaluation that administered 25 acetaminophen after the equivalent of the</p>
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<p>1 case, did you evaluate these animal studies 2 based on effects related to 3 neurodevelopmental orders {sic} broadly or 4 just ASD or ADHD specifically? 5 MS. HUNT: Objection. Form. 6 You can answer. 7 THE WITNESS: Animals don't 8 have ADHD or autism, so, accordingly, 9 I can't just -- I had to -- you know, 10 my catchment for the preclinical 11 studies has to include 12 neurodevelopmental search terms that 13 extend beyond ASD and ADHD. So it's 14 beyond just ASD and ADHD. 15 QUESTIONS BY MR. PADGETT: 16 Q. Okay. And then you used the 17 term "perinatal APAP exposure" there. 18 Can you define what you mean by 19 perinatal there? 20 A. So the exposure window includes 21 early postnatal exposures as well. 22 Q. And for mice and rats, can you 23 tell me where the postnatal window ends if 24 you're talking equivalent to human gestation 25 and neurodevelopment?</p>	<p>1 human gestational neurodevelopmental period 2 of PN 10 or PN 14? 3 A. There are studies that continue 4 the exposure beyond that window, but the 5 requirement was the exposure needed to begin 6 before that early postnatal period. 7 Q. I'll probably butcher the 8 pronunciation here. There's a series of rat 9 studies, the Blecharz-Klin studies. There's 10 two, 2015, two studies, 2016, 2017, 2018 and 11 2019. 12 In those studies, the rats were 13 dosed until they were two months old, 60 days 14 old, right? 15 A. Yes. 16 Q. And if you could refer to 17 page 48 of your report, PN 60, postnatal day 18 60, is the equivalent of a young adult. 19 Agree? 20 A. I would agree with that. 21 In my narrative review of those 22 studies, I acknowledge that extension of that 23 window, clearly. 24 Q. And you mentioned that. 25 Did you knock off any points in</p>

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<p>1 your scoring evaluation for that?</p> <p>2 A. I don't recall.</p> <p>3 Q. Is your -- is your response</p> <p>4 that you do not recall knocking off points or</p> <p>5 that you don't recall whether you did?</p> <p>6 A. I do not recall whether that</p> <p>7 was a scorable criterion or not, the exposure</p> <p>8 window.</p> <p>9 Q. Okay.</p> <p>10 A. I do not believe it was.</p> <p>11 Q. You agree that administration</p> <p>12 of acetaminophen at -- in a rodent at two</p> <p>13 months old does not correspond to human</p> <p>14 gestation, right?</p> <p>15 MS. HUNT: Object to form.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: Exposure starting</p> <p>18 at two months of age would certainly</p> <p>19 be well outside of the exposure</p> <p>20 window, but these animals were exposed</p> <p>21 prenatally in addition to postnatally.</p> <p>22 QUESTIONS BY MR. PADGETT:</p> <p>23 Q. So there's a couple of studies</p> <p>24 that you excluded. There's a long</p> <p>25 footnote 7. Do you remember a long footnote</p>	<p>1 A. That sounds about right.</p> <p>2 Q. And if you dose the rats all</p> <p>3 the way up to 60, we're talking another</p> <p>4 45 days or so of post-human equivalent</p> <p>5 gestation dosing, right?</p> <p>6 A. I'll grant that, yeah.</p> <p>7 Q. And the testing, behavioral and</p> <p>8 biochemical testing, in Blecharz-Klin in</p> <p>9 those series of studies was immediately after</p> <p>10 the last dosing at 60 days generally.</p> <p>11 Is that correct?</p> <p>12 A. It depends on the study. I</p> <p>13 don't think they were all at 60 days.</p> <p>14 Q. Were many?</p> <p>15 A. I think some of them began --</p> <p>16 began earlier.</p> <p>17 Q. All right.</p> <p>18 A. Some of the biochemical ones</p> <p>19 started earlier, I thought.</p> <p>20 Q. In many of these studies,</p> <p>21 though, the rats were dosed longer, like</p> <p>22 45 days longer, than the human equivalent of</p> <p>23 gestation and tested right after that dosing</p> <p>24 ended, correct?</p> <p>25 A. They may have been, yeah.</p>
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<p>1 7 --</p> <p>2 A. I do.</p> <p>3 Q. -- of studies you excluded?</p> <p>4 The Ishida 2007, Viswanathan</p> <p>5 2019 studies, you excluded those because they</p> <p>6 involved administration of acetaminophen in</p> <p>7 four- to five-week-old rodents, right?</p> <p>8 A. Yes.</p> <p>9 Q. And your basis for excluding</p> <p>10 those but not the Blecharz-Klin series of</p> <p>11 studies is because the Ishida and Viswanathan</p> <p>12 studies didn't involve the equivalent of</p> <p>13 human gestation dosing?</p> <p>14 A. The difference between those</p> <p>15 studies is that any effects of acetaminophen</p> <p>16 would be solely attributable to adult</p> <p>17 exposures.</p> <p>18 Q. So if we talk -- I think you</p> <p>19 reference in your report that 20 -- that rat</p> <p>20 gestation is 23 days, right?</p> <p>21 A. Approximately.</p> <p>22 Q. Okay. If we add 10 days or</p> <p>23 14 days on for postnatal equivalent of the</p> <p>24 third trimester of human gestation, that</p> <p>25 would be 33, 37 days, right?</p>	<p>1 I'll also point out that if</p> <p>2 you're doing an observational epidemiological</p> <p>3 study, those individuals that are followed</p> <p>4 up, they're still getting acetaminophen</p> <p>5 postnatal as well. So it's -- it's not --</p> <p>6 it's ecologically relevant in some ways as</p> <p>7 well.</p> <p>8 Q. In this Blecharz-Klin series of</p> <p>9 studies, how are you able to determine -- how</p> <p>10 were you able to determine whether the</p> <p>11 effects observed in those studies occurred</p> <p>12 from those -- the dosing up through PN 10 or</p> <p>13 PN 14 versus the dosing from days 15 to 60?</p> <p>14 MS. HUNT: Object to form.</p> <p>15 You can answer.</p> <p>16 THE WITNESS: In the -- in the</p> <p>17 Blecharz-Klin studies, they do not</p> <p>18 have controls that would allow to</p> <p>19 discriminate the exact time point when</p> <p>20 the cellular, molecular, behavioral</p> <p>21 perturbation would occur.</p> <p>22 On the other hand, there's</p> <p>23 still strengths in these studies</p> <p>24 because it's still demonstrating that</p> <p>25 these prolonged exposures starting in</p>

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<p>1 the prenatal periods are disturbing</p> <p>2 biochemical and behavioral changes.</p> <p>3 Now, it does limit the critical</p> <p>4 window determination, these postnatal</p> <p>5 exposures as well, and that's why I</p> <p>6 fully acknowledge in my report the</p> <p>7 limitations of these studies. I</p> <p>8 acknowledge fully that that is a</p> <p>9 limitation, the post -- these</p> <p>10 postnatal windows as well.</p> <p>11 QUESTIONS BY MR. PADGETT:</p> <p>12 Q. But again, we don't know how --</p> <p>13 you don't recall how that affected your</p> <p>14 scoring in your weight of evidence analysis,</p> <p>15 correct?</p> <p>16 MS. HUNT: Object to form.</p> <p>17 You can answer.</p> <p>18 THE WITNESS: The scoring</p> <p>19 system is to discuss the rigorousness</p> <p>20 of the study design. The scoring is</p> <p>21 not to -- is not -- is not to -- is</p> <p>22 not intended to -- the point of the</p> <p>23 scoring is not to be able to tell you</p> <p>24 whether every single study that's a</p> <p>25 part of the weight of the evidence is</p>	<p>1 evidence analysis?</p> <p>2 A. Dosing?</p> <p>3 Q. Yes.</p> <p>4 A. Whether it had multiple doses</p> <p>5 or not, yes.</p> <p>6 Q. But things like dosing duration</p> <p>7 or dosing amount, you didn't adjust the</p> <p>8 points given for a study based on differences</p> <p>9 there, just based on whether there are</p> <p>10 multiple doses given?</p> <p>11 MS. HUNT: Object to the form</p> <p>12 of the question.</p> <p>13 You can answer.</p> <p>14 THE WITNESS: There's an</p> <p>15 infinite number of ways that I could</p> <p>16 have designed the rubric. This is the</p> <p>17 system that I came up with. The</p> <p>18 exposure window was an inclusion</p> <p>19 criteria for the studies.</p> <p>20 If pre -- if gestational dosing</p> <p>21 was included for acetaminophen and</p> <p>22 neurodevelopmental relevant outcomes</p> <p>23 were in the study, then it was</p> <p>24 included in the weight of evidence.</p> <p>25 That was not a scored criteria.</p>
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<p>1 suitable for understanding</p> <p>2 acetaminophen and prenatal exposure</p> <p>3 windows and neurodevelopmental health</p> <p>4 outcomes.</p> <p>5 The scoring system that I came</p> <p>6 up with is to understand the</p> <p>7 characteristics of the study and give</p> <p>8 a transparency into my work into</p> <p>9 understanding the parameters of</p> <p>10 controls and those sorts of</p> <p>11 characteristics of the study.</p> <p>12 So not every aspect of the</p> <p>13 study got a score, but that's why</p> <p>14 there's a narrative box that came with</p> <p>15 it to where I disclose, like, here are</p> <p>16 strengths and weaknesses of these</p> <p>17 studies as well.</p> <p>18 So not every aspect of the</p> <p>19 study has a score -- a score-driving</p> <p>20 aspect to it. It's unrealistic to</p> <p>21 expect that. This would be a</p> <p>22 thousand-page report if it did.</p> <p>23 QUESTIONS BY MR. PADGETT:</p> <p>24 Q. Dosing was given a score,</p> <p>25 though, right, as part of your weight of the</p>	<p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. If you could turn to page 47 of</p> <p>3 your report.</p> <p>4 A. Okay.</p> <p>5 Q. It's 46 to 47. There's a</p> <p>6 paragraph describing this -- what leads to a</p> <p>7 chart, a figure. And you've got different --</p> <p>8 differently grayed or darkened dosing for a</p> <p>9 mouse from therapeutic sublethal toxic dose,</p> <p>10 lethal toxic dose, if untreated, and evidence</p> <p>11 of neurodevelopmental, neurological damage.</p> <p>12 Do you see that?</p> <p>13 A. I see it.</p> <p>14 Q. Okay. The therapeutic dose you</p> <p>15 list there for mice is 200 milligrams per</p> <p>16 kilogram, correct?</p> <p>17 A. That's correct.</p> <p>18 Q. Okay. And that's the top end.</p> <p>19 That's the outer edge of the therapeutic dose</p> <p>20 you've listed there, right?</p> <p>21 A. It is.</p> <p>22 Q. Okay. And lethal toxic dose</p> <p>23 appears to be potentially anything above</p> <p>24 350 milligrams per kilogram; is that right?</p> <p>25 A. It's -- it's a spectrum,</p>

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<p style="text-align: right;">Page 134</p> <p>1 because it's hard to find exact numbers. 2 Q. Would you agree that the line 3 that you drew here on lethal toxic dose of 4 350 milligrams per kilograms for mice in that 5 figure? 6 A. I think it was maybe 325. 7 Q. Okay. 8 A. The reference numbers are 3 and 9 4 there. 10 Q. So 325. 11 A. I think those are coming from 12 overdose studies where they're looking for 13 liver damage. I don't think they're 14 necessarily lethality studies, but... 15 Q. It's listed as lethal toxic 16 dose, though, right, on Figure 23? 17 MS. HUNT: Object to the form 18 of the question. 19 You can answer. 20 THE WITNESS: If you look 21 inside of the box on Figure 2.3, it 22 says, "Note: Concentrations in 23 delineations are approximate based on 24 a survey of literature for oral. They 25 do not account for individual strain</p>	<p style="text-align: right;">Page 136</p> <p>1 MR. PADGETT: This question? 2 QUESTIONS BY MR. PADGETT: 3 Q. What was the dose used in 4 Lichtensteiger? 5 A. I'm looking. 6 Q. As far as acetaminophen. 7 MS. HUNT: Counsel, do you have 8 a copy for me or no? 9 MR. PADGETT: Sorry. 10 MS. HUNT: Thank you. 11 MR. PADGETT: I believe it's -- 12 THE WITNESS: Buried in this 13 paper, yeah. 14 QUESTIONS BY MR. PADGETT: 15 Q. -- Table 1. 16 A. It's Table 1. 17 Q. The... 18 A. 360. 19 Q. That was -- that's the -- that 20 was the -- 360 milligrams per kilogram for 21 acetaminophen alone, correct? 22 A. Yes. 23 Q. Okay. But this isn't -- this 24 was included in your weight of analysis? 25 A. It was.</p>
<p style="text-align: right;">Page 135</p> <p>1 differences. These are meant to be 2 approximate." 3 QUESTIONS BY MR. PADGETT: 4 Q. Lichtensteiger 2015 only 5 administered a dose of 360 milligrams per 6 kilogram, right? 7 A. Okay. I'd have to look. 8 (Pearson Exhibit 71 marked for 9 identification.) 10 QUESTIONS BY MR. PADGETT: 11 Q. I'm going to hand you what's 12 been marked as Exhibit 71. 13 A. Okay. 14 Q. Is that the Lichtensteiger 2015 15 study? 16 A. It is. 17 MS. HUNT: Counsel, before we 18 start on a new study, I think we've 19 been going about an hour and 20 20 minutes. 21 MR. PADGETT: Sure. 22 MS. HUNT: Can we take a break? 23 MR. PADGETT: Can we just 24 finish this one? 25 MS. HUNT: Sure.</p>	<p style="text-align: right;">Page 137</p> <p>1 Q. Okay. We already talked about 2 Klein 20 -- or actually I'm gonna -- 3 MS. HUNT: Can we take a break? 4 MR. PADGETT: Yeah, let's go 5 ahead and take a break. 6 VIDEOGRAPHER: The time right 7 now is 11:18 a.m., and we're off the 8 record. 9 (Off the record at 11:18 a.m.) 10 VIDEOGRAPHER: The time right 11 now is 11:36 a.m., and we're back on 12 the record. 13 QUESTIONS BY MR. PADGETT: 14 Q. Dr. Pearson, back from a little 15 break. 16 Page 4 of your report. And I 17 should be keeping better track, but I believe 18 that was... 19 MS. KAPKE: It's 65. 20 QUESTIONS BY MR. PADGETT: 21 Q. Exhibit 65, your amended 22 report, at page 4. 23 You have a statement about 24 "preclinical studies account for confounding 25 that may be present in epidemiology studies."</p>

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<p>1 And --</p> <p>2 A. Can you show exactly where that</p> <p>3 is or tell me where exactly that was?</p> <p>4 Q. You know what, strike that.</p> <p>5 I'd like you to turn to</p> <p>6 pages 60 -- page 66, please.</p> <p>7 A. Okay.</p> <p>8 Q. And you talk about your weight</p> <p>9 of analysis methodology. And there you list</p> <p>10 five steps: problem; formulation, where you</p> <p>11 develop your hypothesis; evidence collection,</p> <p>12 where you establish lines of evidence and</p> <p>13 knowledge gaps; evidence evaluation,</p> <p>14 determine data reliability, uncertainty and</p> <p>15 relevance; and evidence-weighting, where you</p> <p>16 assign weight of evidence; evidence</p> <p>17 integration and reporting, weight of evidence</p> <p>18 conclusions, when you examine evidence</p> <p>19 coherence and the impact of uncertainty.</p> <p>20 Those are the five steps of</p> <p>21 your weight of evidence analysis?</p> <p>22 Is that --</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And you talk about</p> <p>25 problem formulation on page 67.</p>	<p>1 correct?</p> <p>2 A. It says, "perhaps most</p> <p>3 important," yes.</p> <p>4 Q. Okay. If you'd jump ahead to</p> <p>5 the data reliability discussion at pages 72</p> <p>6 to 76, please.</p> <p>7 A. I'm there.</p> <p>8 Q. Okay. And you discuss the</p> <p>9 importance of assessing quality and quantity,</p> <p>10 or sufficiency, and the consistency of data</p> <p>11 across the lines of evidence, right?</p> <p>12 A. That's included in this area,</p> <p>13 yes.</p> <p>14 Q. And you state, "The sufficiency</p> <p>15 refers to the quantity of data that addresses</p> <p>16 the hypothesis or problem, and consistency</p> <p>17 refers to the level of consensus and</p> <p>18 concordance among the data in the particular</p> <p>19 line of evidence."</p> <p>20 Right?</p> <p>21 A. I'm not sure where it says that</p> <p>22 exact statement, but --</p> <p>23 Q. Page 73.</p> <p>24 A. Consistency refers to the level</p> <p>25 of consensus and concordance amongst the data</p>
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<p>1 Your problem formulation</p> <p>2 evaluated in utero exposure to acetaminophen</p> <p>3 and neurodevelopmental disorders generally,</p> <p>4 right?</p> <p>5 A. It's -- it starts by saying</p> <p>6 neurodevelopmental disorders, including ASD</p> <p>7 and ADHD.</p> <p>8 Q. Okay. But it was not specific</p> <p>9 to ADHD and ASD, right?</p> <p>10 MS. HUNT: Object to the form</p> <p>11 of the question.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: It goes back to</p> <p>14 my previous testimony that in</p> <p>15 preclinical literature, the</p> <p>16 preclinical studies have limitations</p> <p>17 in terms of being specific to ASD and</p> <p>18 ADHD because animal models -- they're</p> <p>19 animal models and in vitro models.</p> <p>20 QUESTIONS BY MR. PADGETT:</p> <p>21 Q. And then on page 69, you talk</p> <p>22 about evidence evaluation, and you</p> <p>23 characterize it as arguably the most</p> <p>24 important step in the weight of the</p> <p>25 analysis -- weight of evidence analysis,</p>	<p>1 in a particular level of evidence.</p> <p>2 Q. Aside from a discussion -- and</p> <p>3 I think it's on page 128 of your report --</p> <p>4 consistency is not necessarily necess -- or</p> <p>5 not necessarily needed. You don't discuss</p> <p>6 consistency among the studies included in</p> <p>7 each of your lines of evidence in this</p> <p>8 report, right?</p> <p>9 MS. HUNT: Objection. Form.</p> <p>10 You can answer.</p> <p>11 THE WITNESS: You're asking</p> <p>12 whether I discuss consistency within</p> <p>13 each of the lines of evidence?</p> <p>14 QUESTIONS BY MR. PADGETT:</p> <p>15 Q. Right.</p> <p>16 A. I do. There's a table at the</p> <p>17 end of each line of evidence where</p> <p>18 consistency is discussed.</p> <p>19 Q. And you're talking about the</p> <p>20 mouse and the rat tables?</p> <p>21 A. Well, there's the -- there's</p> <p>22 the lines of evidence and then tables, and</p> <p>23 they discuss -- take us there.</p> <p>24 Q. Let me ask it this way. Do you</p> <p>25 discuss particularly -- particular</p>

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<p style="text-align: right;">Page 142</p> <p>1 inconsistencies between studies on certain</p> <p>2 endpoint findings across these studies?</p> <p>3 MS. HUNT: Objection. Form.</p> <p>4 You can answer.</p> <p>5 THE WITNESS: So the way that I</p> <p>6 perform my weight of evidence was not</p> <p>7 to contrast each and individual --</p> <p>8 each and every individual study to see</p> <p>9 how they do and do not support one</p> <p>10 another or whether the -- each</p> <p>11 individual data set contrasts each</p> <p>12 other. That was not my goal.</p> <p>13 QUESTIONS BY MR. PADGETT:</p> <p>14 Q. So, and correct me if I am</p> <p>15 wrong, I don't recall a specific discussion</p> <p>16 of, say, rat study X we found this finding on</p> <p>17 a particular endpoint, which -- and address</p> <p>18 an inconsistency with rat study Y that found</p> <p>19 no change or something -- a change in a</p> <p>20 different direction.</p> <p>21 You didn't do that kind of</p> <p>22 study-by-study analysis, right?</p> <p>23 MS. HUNT: Object to the form</p> <p>24 of the question.</p> <p>25 You can answer.</p>	<p style="text-align: right;">Page 144</p> <p>1 outcomes.</p> <p>2 It's not to -- again, it's not</p> <p>3 what you're suggesting.</p> <p>4 QUESTIONS BY MR. PADGETT:</p> <p>5 Q. Let me give you an example.</p> <p>6 Let's take the five-choice serial-reaction</p> <p>7 time test, which is focused on attention as</p> <p>8 it relates to ADHD. That's the focus the --</p> <p>9 of that particular assay in the animal model,</p> <p>10 right?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. This is just an example.</p> <p>13 Did you do an analysis of,</p> <p>14 across studies, the consistency for the</p> <p>15 endpoints in terms of changes seen or no</p> <p>16 changes seen on an endpoint like that --</p> <p>17 MS. HUNT: Object to form.</p> <p>18 QUESTIONS BY MR. PADGETT:</p> <p>19 Q. -- as a part of your weight of</p> <p>20 the evidence evaluation?</p> <p>21 MS. HUNT: Object to form.</p> <p>22 You can answer.</p> <p>23 THE WITNESS: That was not my</p> <p>24 goal with my weight of -- weight of</p> <p>25 evidence analysis.</p>
<p style="text-align: right;">Page 143</p> <p>1 THE WITNESS: The example that</p> <p>2 you gave would not -- would not be an</p> <p>3 appropriate way that an expert would</p> <p>4 do this, for multiple reasons.</p> <p>5 One, as I explained multiple</p> <p>6 times, the directionality is not an</p> <p>7 appropriate way to look for things.</p> <p>8 Directionality is something that we --</p> <p>9 that's sort of a face validity thing.</p> <p>10 Face validity is kind of lowest level</p> <p>11 of evidence for animal models in</p> <p>12 neuropsychiatric disorders. These</p> <p>13 studies aren't necessarily engineered</p> <p>14 to fill gaps of other studies.</p> <p>15 The weight of an evidence is to</p> <p>16 look for the cumulative data across</p> <p>17 all of the different studies on the</p> <p>18 whole. It's not -- the goal of this</p> <p>19 endeavor isn't to say, are all of the</p> <p>20 puzzle pieces filled. It's to say</p> <p>21 that is there a total -- an abundance</p> <p>22 of evidence to suggest that</p> <p>23 acetaminophen is a developmental</p> <p>24 neurotoxicant that elicits the effects</p> <p>25 that are relevant to these health</p>	<p style="text-align: right;">Page 145</p> <p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. I understand it's not your</p> <p>3 goal, but did -- you say it's not your goal,</p> <p>4 and then you -- so did not do that because</p> <p>5 that wasn't your goal, right?</p> <p>6 MS. HUNT: Objection. Asked</p> <p>7 and answered.</p> <p>8 You can answer it again.</p> <p>9 MR. PADGETT: Object to form</p> <p>10 only, please.</p> <p>11 MS. HUNT: My objections have</p> <p>12 been appropriate, and in fact</p> <p>13 conservative, compared to what some of</p> <p>14 the counsel for Johnson & Johnson have</p> <p>15 done. And I'm not -- I'm happy to</p> <p>16 argue with you about it if you want to</p> <p>17 take up more time on your record.</p> <p>18 There's nothing inappropriate</p> <p>19 about my objections. I'd like to get</p> <p>20 back to the questioning.</p> <p>21 MR. PADGETT: Well, I'll just</p> <p>22 remind you to object to form only, and</p> <p>23 we don't -- you know, if it continues</p> <p>24 beyond that, we don't want to have to</p> <p>25 deal with the Court.</p>

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<p style="text-align: right;">Page 146</p> <p>1 MS. HUNT: We'll see.</p> <p>2 QUESTIONS BY MR. PADGETT:</p> <p>3 Q. Go ahead.</p> <p>4 A. The example that you're giving</p> <p>5 would not -- is not pertinent to the mandate</p> <p>6 that I was given. It would not be necessary.</p> <p>7 Q. So you didn't feel it was</p> <p>8 necessary and therefore you did not do that</p> <p>9 type of cross-studies analysis of</p> <p>10 inconsistencies, correct?</p> <p>11 MS. HUNT: Again, objection.</p> <p>12 Asked and answered.</p> <p>13 You can answer.</p> <p>14 THE WITNESS: So in my report,</p> <p>15 I do discuss where there's concordance</p> <p>16 across studies.</p> <p>17 QUESTIONS BY MR. PADGETT:</p> <p>18 Q. Do you discuss whether there's</p> <p>19 inconsistencies across studies?</p> <p>20 MS. HUNT: Objection. Form.</p> <p>21 You can answer.</p> <p>22 THE WITNESS: I do not recall</p> <p>23 offhand where I discuss whether there</p> <p>24 is or isn't inconsistencies.</p> <p>25 But a weight of evidence</p>	<p style="text-align: right;">Page 148</p> <p>1 exercise, did you rely on a peer-reviewed,</p> <p>2 validated, preexisting scoring system that</p> <p>3 was already in existence?</p> <p>4 MS. HUNT: Object to form.</p> <p>5 You can answer.</p> <p>6 THE WITNESS: I relied on the</p> <p>7 same evaluation system that I use when</p> <p>8 I peer-review grants and other</p> <p>9 publications. It's the same way that</p> <p>10 I evaluate other studies.</p> <p>11 QUESTIONS BY MR. PADGETT:</p> <p>12 Q. You use a scoring system when</p> <p>13 you peer-review grants or articles?</p> <p>14 A. Yes. That's pretty common,</p> <p>15 actually.</p> <p>16 Q. And are you saying it's similar</p> <p>17 to what you did in this weight of analysis</p> <p>18 evaluation?</p> <p>19 MS. HUNT: Object to form.</p> <p>20 You can answer.</p> <p>21 THE WITNESS: It's pretty</p> <p>22 analogous to evaluation criteria for</p> <p>23 any evaluation of publications or</p> <p>24 grants.</p> <p>25</p>
<p style="text-align: right;">Page 147</p> <p>1 analysis does not require</p> <p>2 inconsistencies of all studies to be</p> <p>3 evaluated.</p> <p>4 QUESTIONS BY MR. PADGETT:</p> <p>5 Q. Data quality, I think, is</p> <p>6 discussed pages 73 to 79 of your report.</p> <p>7 For assessing data quality,</p> <p>8 would you agree that you created your own</p> <p>9 scoring system?</p> <p>10 A. I would not agree that for</p> <p>11 assessing data quality I created my own</p> <p>12 scoring system.</p> <p>13 Q. Can you identify a particular</p> <p>14 peer-reviewed, preexisting scoring system</p> <p>15 that you used? And I'm talking specifically</p> <p>16 as to a scoring system in putting together</p> <p>17 your scoring system in your weight of</p> <p>18 analysis -- weight of evidence analysis.</p> <p>19 A. As I stated previously, the</p> <p>20 study design attributes, I put numerical</p> <p>21 parameters to those to add transparency to my</p> <p>22 evaluation of those.</p> <p>23 Q. That's in your report. I</p> <p>24 understand that.</p> <p>25 My question is, in doing that</p>	<p style="text-align: right;">Page 149</p> <p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. Can you --</p> <p>3 A. Grants submitted to granting</p> <p>4 agencies are scored on scoring systems, like</p> <p>5 a 1 to 5 system or a 1 to 2 system.</p> <p>6 It's the same for peer-reviewed</p> <p>7 publications. It's numerical scoring systems</p> <p>8 based on innovation, based on quality of</p> <p>9 controls, and it's a very similar type of</p> <p>10 scoring system.</p> <p>11 Q. And have you done that exercise</p> <p>12 outside of this litigation in the same manner</p> <p>13 that you did it with regard to your scoring</p> <p>14 system here in your weight of analysis -- or</p> <p>15 weight of evidence analysis described in your</p> <p>16 report?</p> <p>17 A. I -- as I said, it's fairly</p> <p>18 analogous. Just as I said, I just co-opted</p> <p>19 it here to add transparency to the way that I</p> <p>20 evaluated the preclinical literature for the</p> <p>21 purposes of the weight of evidence.</p> <p>22 And then in terms of</p> <p>23 publications, I'm using the OECD framework,</p> <p>24 which is a scientific approach to performing</p> <p>25 a systematic review.</p>

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<p>1 Q. You state on I think it's</p> <p>2 page 74 your scoring template that you used</p> <p>3 for each study. The parameters were</p> <p>4 direction of effect, controls, sample size,</p> <p>5 outcomes, multi-dose, whether there was</p> <p>6 multi-dosing, blinding, and bias conflict</p> <p>7 flag.</p> <p>8 Is that right?</p> <p>9 A. That's what's stated here.</p> <p>10 Q. Okay. You did not define in</p> <p>11 your report what an insufficient control is,</p> <p>12 right?</p> <p>13 MS. HUNT: Object to form of</p> <p>14 the question.</p> <p>15 You can answer.</p> <p>16 THE WITNESS: Well, in the text</p> <p>17 I refer to the table and give a little</p> <p>18 bit of context into what the</p> <p>19 parameters are that go into it.</p> <p>20 QUESTIONS BY MR. PADGETT:</p> <p>21 Q. What page are you referring to?</p> <p>22 A. Let me find it. I think it</p> <p>23 might have gotten out of place accidentally.</p> <p>24 Q. I can't imagine that, a</p> <p>25 130-page report.</p>	<p>1 you're referring to in some of the -- your</p> <p>2 summaries of the studies, did you explain</p> <p>3 across your weight of evidence analysis what</p> <p>4 the differences between acceptable and a good</p> <p>5 control are?</p> <p>6 MS. HUNT: Object to form.</p> <p>7 You can answer.</p> <p>8 THE WITNESS: I don't think I</p> <p>9 provided much other explanation of</p> <p>10 that. But the thing you have to keep</p> <p>11 in mind is that the weight of evidence</p> <p>12 methodology ultimately requires expert</p> <p>13 knowledge, and that's what I'm</p> <p>14 bringing, is my expert knowledge and</p> <p>15 my, you know, almost 20 years of</p> <p>16 peer-reviewing hundreds of</p> <p>17 publications, writing dozens of</p> <p>18 publications. So I'm bringing that</p> <p>19 knowledge in my expert ability to</p> <p>20 adjudicate on that.</p> <p>21 QUESTIONS BY MR. PADGETT:</p> <p>22 Q. In your description of your</p> <p>23 weight of analysis -- weight of evidence</p> <p>24 analysis, you do not define what an</p> <p>25 acceptable sample size is, correct?</p>
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<p>1 A. I think it accidentally got</p> <p>2 shifted around. Bear with me, please.</p> <p>3 Maybe I didn't expand on it any</p> <p>4 further than what's in the table.</p> <p>5 Q. And which table are you</p> <p>6 referring to?</p> <p>7 A. Table 1.</p> <p>8 It's the blank scoring</p> <p>9 template.</p> <p>10 Q. Okay. Table 1 is the extent of</p> <p>11 your explanation of -- or definitions or</p> <p>12 explanation of these -- the parameters that</p> <p>13 we just discussed?</p> <p>14 A. Not completely. In the</p> <p>15 narrative explanation for a lot of the</p> <p>16 studies, there's oftentimes, but not always,</p> <p>17 but oftentimes there's additional</p> <p>18 clarification as to why a score was given.</p> <p>19 The scores aren't meant to be</p> <p>20 used as an actual grade, if you will. It's</p> <p>21 just meant to give sort of an ultimate</p> <p>22 positive or negative for a weight towards</p> <p>23 there's evidence for or to the contrary in</p> <p>24 the end.</p> <p>25 Q. And beyond this table and what</p>	<p>1 A. I give some descriptions of</p> <p>2 that in my expert report.</p> <p>3 Q. You don't in any way</p> <p>4 quantitatively define, depending on the type</p> <p>5 of study, what an acceptable sample size is,</p> <p>6 right?</p> <p>7 MS. HUNT: Objection. Asked</p> <p>8 and answered.</p> <p>9 You can answer.</p> <p>10 THE WITNESS: I don't recall</p> <p>11 offhand where exactly it is, but I</p> <p>12 give some general parameters as to</p> <p>13 what's oftentimes needed. But it</p> <p>14 really is -- it depends on the study.</p> <p>15 It's prescriptive to the study what</p> <p>16 sorts of sample sizes are oftentimes</p> <p>17 needed.</p> <p>18 QUESTIONS BY MR. PADGETT:</p> <p>19 Q. Can you explain to me with</p> <p>20 regard to outcomes what distinguishes a poor,</p> <p>21 moderate and good quality outcome as</p> <p>22 referenced here on page 74, Table 1?</p> <p>23 A. The quality of the outcomes</p> <p>24 might have to do with the extent of the</p> <p>25 outcomes. So a study might have only one</p>

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<p>1 outcome that's relevant, but because it's one 2 outcome, the score might not be as high. 3 Another study might have 4 outcomes that are on their own not quite as 5 relevant, but because the study has more of 6 them, the outcome score might be higher. 7 Another study might have only a 8 few outcomes, but each of them are very, very 9 high. 10 So to give you an example of a 11 study that's looking for ASD-relevant 12 behavioral outcomes or ASD-like outcomes as a 13 function of acetaminophen exposures, if they 14 have the three-chamber socialability test and 15 they have gene expression and they have, you 16 know -- let's see, what would be another good 17 example -- they have ultrasonic 18 vocalizations, maybe they only have those 19 three outcome variables, but those are highly 20 relevant, highly important variables 21 themselves, so the outcome score would be 22 higher. I don't think there's a study that 23 had those three things specifically. 24 So it -- you know, there's not 25 one hard-and-fast rule that says you have to</p>	<p>1 sure I understand your question. 2 So are you asking about whether 3 the outcome score that I give depends 4 on what results they find? 5 QUESTIONS BY MR. PADGETT: 6 Q. Yes. 7 A. The score that I give is 8 independent of the outcome, what they find. 9 It's the measures that they -- 10 Q. Yeah. 11 A. -- choose to use. The score is 12 independent of what they find. 13 Q. And let me ask this. Whether 14 or not you put a study on the plus side of 15 the scale or the negative side of the scale, 16 did you do an analysis of the consistency 17 among assays for particular behavioral 18 endpoints within a study? 19 MS. HUNT: Object to form. 20 You can answer. 21 THE WITNESS: My understanding 22 of your question is whether the study 23 ended up on the plus end of the scale 24 or on the negative end of the scale 25 had anything to do with the</p>
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<p>1 have three outcomes. You can have one 2 outcome that's highly -- high quality, but 3 you still might have a moderate outcome score 4 because you have fewer high quality. You 5 might have a higher number that are lower 6 quality, for instance. 7 So it's multi-dimensional, the 8 way that this is calculated. 9 Q. And did you -- and so is 10 outcome as used here, outcomes, is that 11 essentially the same as endpoint findings in 12 a study? 13 A. Yeah. That's fair. 14 Q. Okay. And within individual 15 studies on various endpoint findings, did you 16 do an analysis for purposes of scoring of 17 whether those endpoint findings, there were 18 more than one for a particular behavioral 19 effect, were consistent within the study 20 pursuant to the animal models that you laid 21 out at pages 39 to 46 of your report? 22 MS. HUNT: Object to the form 23 of the question. 24 You can answer. 25 THE WITNESS: I want to make</p>	<p>1 consistency of the measures within the 2 outcomes. 3 Is that a fair -- 4 QUESTIONS BY MR. PADGETT: 5 Q. Yes. 6 A. No. It has to do with whether 7 the effects within those outcomes suggest 8 that acetaminophen affects 9 neurodevelopmental, neurochemical or 10 neurobehavioral outcomes that are relevant to 11 ASD-like or ADHD-like health. 12 Q. So going beyond one specific 13 behavioral effect, I'm going to provide you a 14 hypothetical. 15 If a study showed one assay 16 with a statistically significant finding with 17 regard to increased activity, another finding 18 on increased activity that was no change -- 19 are you following me? That -- that's the 20 activity domain -- and then another part of 21 that same study looked at -- or another set 22 of assays looked at inattention and 23 impulsivity and found no changes consistent 24 with the ADHD model, would you put that one 25 effect of increased activity as sufficient to</p>

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<p>1 put it in the plus column?</p> <p>2 MS. HUNT: Objection. Form.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: In this</p> <p>5 particular -- this hypothetical that</p> <p>6 you've given me, if there was such a</p> <p>7 study that looked at some measure of</p> <p>8 impulsivity and attention and</p> <p>9 activity, and in two tests of</p> <p>10 activity -- and one of them found</p> <p>11 increased activity and another one no</p> <p>12 change, and then the other test found</p> <p>13 no change --</p> <p>14 QUESTIONS BY MR. PADGETT:</p> <p>15 Q. For impulsivity and attention,</p> <p>16 correct.</p> <p>17 A. -- it would go in the plus --</p> <p>18 Q. Okay.</p> <p>19 A. -- certainly.</p> <p>20 Q. Okay. In pages 76 and 77 of</p> <p>21 your report, you discuss different methods of</p> <p>22 administration commonly used in preclinical</p> <p>23 developmental neurotoxicity studies, right?</p> <p>24 A. I see this.</p> <p>25 Q. Okay. Would you agree that</p>	<p>1 would result in lower concentration, correct?</p> <p>2 MS. HUNT: Object to form.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: It's hard to</p> <p>5 answer that question because it's --</p> <p>6 it depends on the route of injection.</p> <p>7 If you -- to give you an example.</p> <p>8 So if you give an intravenous</p> <p>9 versus oral, the Cmax is certainly</p> <p>10 very different. There's data that</p> <p>11 supports that. But, for instance, the</p> <p>12 area under the curve is very similar.</p> <p>13 So, you know, it's -- are you</p> <p>14 asking about bioavailability? Are you</p> <p>15 asking about area under the curve?</p> <p>16 The first-pass metabolism is</p> <p>17 different. The Cmax is different.</p> <p>18 So route of administration is</p> <p>19 an important consideration, but</p> <p>20 bioavailability can be very similar.</p> <p>21 QUESTIONS BY MR. PADGETT:</p> <p>22 Q. You agree that drug and</p> <p>23 metabolite concentrations from an injection</p> <p>24 would be different from those that would</p> <p>25 occur via oral exposure?</p>
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<p>1 doses by injections bypass the liver in</p> <p>2 first-pass metabolism that would occur if a</p> <p>3 drug was administered orally?</p> <p>4 A. Injection of drugs, a lot of</p> <p>5 the initial bolus of that drug would bypass</p> <p>6 first-pass, but it'll get there eventually.</p> <p>7 Just takes a little bit longer.</p> <p>8 Q. At a -- depending on the</p> <p>9 metabolism associated, it would be a lower</p> <p>10 amount, correct?</p> <p>11 A. Are you asking if the amount of</p> <p>12 the drug would be -- the amount of the drug</p> <p>13 that's metabolized would be lower?</p> <p>14 Q. In a -- if you're going through</p> <p>15 the liver in first-pass metabolism.</p> <p>16 MS. HUNT: Object to form.</p> <p>17 You can answer.</p> <p>18 QUESTIONS BY MR. PADGETT:</p> <p>19 Q. Than an injection route.</p> <p>20 A. Oral versus injection?</p> <p>21 Q. Yes.</p> <p>22 A. The kinetics would certainly be</p> <p>23 different.</p> <p>24 Q. And the kinetics for oral</p> <p>25 involving first-pass metabolism in the liver</p>	<p>1 MS. HUNT: Object to form.</p> <p>2 You can answer.</p> <p>3 THE WITNESS: As I said, the</p> <p>4 bioavailability can be very similar,</p> <p>5 but the Cmax can differ.</p> <p>6 QUESTIONS BY MR. PADGETT:</p> <p>7 Q. And I think after the table on</p> <p>8 page 77 of your report, you note that orally</p> <p>9 administered APAP products are the focus for</p> <p>10 your inquiry and, as such, tests that utilize</p> <p>11 other routes of administration require an</p> <p>12 additional degree of extrapolation.</p> <p>13 Would you agree that the</p> <p>14 majority of the studies included in your</p> <p>15 weight of evidence analysis did not use oral</p> <p>16 administration of acetaminophen?</p> <p>17 A. I don't necessarily agree. It</p> <p>18 depends on the species.</p> <p>19 Q. Well, let's go to --</p> <p>20 A. Many of them use injection. I</p> <p>21 would concede that.</p> <p>22 Q. If we go to page 84 on rat</p> <p>23 studies.</p> <p>24 Seven of the 14 rat studies</p> <p>25 used oral dose exposure route, right?</p>

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<p>1 MS. HUNT: Object to form.</p> <p>2 You can answer.</p> <p>3 THE WITNESS: I see that many</p> <p>4 of them used oral, yes.</p> <p>5 QUESTIONS BY MR. PADGETT:</p> <p>6 Q. Seven of 14, correct?</p> <p>7 A. No, that's not correct.</p> <p>8 Q. Can you explain what --</p> <p>9 A. Gavage is oral.</p> <p>10 Q. Is gavage go -- gavage goes</p> <p>11 through a first pass?</p> <p>12 A. It does.</p> <p>13 Q. Okay. So that would be ten</p> <p>14 total --</p> <p>15 A. Yes.</p> <p>16 Q. -- of 14, right?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And for the mouse</p> <p>19 studies in your chart at page 101, the --</p> <p>20 five of the 15 studies use -- there used</p> <p>21 gavage or oral exposure route, correct?</p> <p>22 A. I think it's actually a</p> <p>23 different number, but it's -- yeah, many of</p> <p>24 them used injection. Many of the mouse</p> <p>25 studies used an injection.</p>	<p>1 different. Page 100.</p> <p>2 A. Threw me off here. Okay.</p> <p>3 On 100 I have Viberg.</p> <p>4 Or are you looking at the</p> <p>5 table?</p> <p>6 Q. I'm looking at the table.</p> <p>7 A. Oh, okay. Yes.</p> <p>8 Q. There are a number of studies</p> <p>9 on your initial report that are not on the</p> <p>10 list of studies on page 100.</p> <p>11 I guess my question is, did you</p> <p>12 make changes to this chart between your</p> <p>13 initial report submitted on -- the first</p> <p>14 report and this amended report?</p> <p>15 A. I do not remember if this chart</p> <p>16 was changed. I believe there was one table</p> <p>17 that was corrected because there was a</p> <p>18 duplication in the -- a table, but there</p> <p>19 wasn't any substance that was changed.</p> <p>20 Q. So as far as mouse studies,</p> <p>21 we're talking three oral, looking at</p> <p>22 page 100, and six injection studies, right?</p> <p>23 A. That is what I see here.</p> <p>24 Q. And Harshaw & Warner is given</p> <p>25 the highest score out of all of these studies</p>
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<p>1 Q. Overall, between the rat and</p> <p>2 the mouse studies, about half of them used</p> <p>3 injection as opposed to gavage or oral,</p> <p>4 right?</p> <p>5 A. On the order of that, yeah.</p> <p>6 Q. Yeah.</p> <p>7 What do you mean by "an</p> <p>8 additional degree of extrapolation" there on</p> <p>9 page 77 of your report?</p> <p>10 A. I'm not sure what I meant with</p> <p>11 that statement. I think -- I think that's --</p> <p>12 I think that's probably something I wrote</p> <p>13 late, and I -- it's a bit nonsensical.</p> <p>14 Q. Would your highest-scored</p> <p>15 study -- and I believe it's page -- it's a</p> <p>16 mouse study, page 101 -- is the Harshaw &</p> <p>17 Warner study. You gave that a 9 total,</p> <p>18 correct?</p> <p>19 A. I think I might be off by</p> <p>20 pages. Oh, I'm -- we're --</p> <p>21 Q. Looking at your amended expert</p> <p>22 report.</p> <p>23 You're right.</p> <p>24 A. Okay.</p> <p>25 Q. The amended one is slightly</p>	<p>1 in your weight of evidence analysis, right?</p> <p>2 A. It is.</p> <p>3 Q. And Harshaw used a subcutaneous</p> <p>4 injection, right?</p> <p>5 A. They used a subcutaneous</p> <p>6 injection.</p> <p>7 Q. Was there any discounting of</p> <p>8 points at all based on the route of injection</p> <p>9 due to that additional degree of</p> <p>10 extrapolation that you mention on page 77 of</p> <p>11 your report?</p> <p>12 MS. HUNT: Object to form.</p> <p>13 You can answer.</p> <p>14 THE WITNESS: No. No</p> <p>15 difference of extrapolation is needed.</p> <p>16 Again, the control animals</p> <p>17 would have received an injection as</p> <p>18 well in this study, so that's</p> <p>19 perfectly controlled for, the</p> <p>20 injection itself. So they -- the</p> <p>21 experimenters have accounted for that</p> <p>22 manipulation itself.</p> <p>23 QUESTIONS BY MR. PADGETT:</p> <p>24 Q. Did all of the studies included</p> <p>25 in -- and you reference that as an important</p>

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<p>1 factor in offsetting any differences in the</p> <p>2 route of administration, is that the controls</p> <p>3 through vehicle received the same -- or water</p> <p>4 received the same type of dosing route,</p> <p>5 right?</p> <p>6 A. It's incredibly important.</p> <p>7 (Pearson Exhibit 73 marked for</p> <p>8 identification.)</p> <p>9 QUESTIONS BY MR. PADGETT:</p> <p>10 Q. Okay. Dr. Pearson, I'm going</p> <p>11 to hand you what's been marked as Exhibit 73</p> <p>12 and ask you if you recognize that study.</p> <p>13 A. I do.</p> <p>14 Q. And that is the Beck 2001</p> <p>15 study, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Does this -- and you can look</p> <p>18 at your summary in your report on it. Does</p> <p>19 this article indicate that if controls were</p> <p>20 gavaged in this study?</p> <p>21 A. Yes. So I noticed in the</p> <p>22 defense expert report that they caught, which</p> <p>23 I may have missed, that they did not use an</p> <p>24 appropriate control in this study.</p> <p>25 Q. Because gavage creates stress</p>	<p>1 been marked as exhibit -- previously marked</p> <p>2 as Exhibit 43. I believe this was from</p> <p>3 Dr. Louie's deposition.</p> <p>4 Do you recognize that study?</p> <p>5 A. I do.</p> <p>6 Q. Does this study indicate --</p> <p>7 study article indicate if controls also</p> <p>8 received enteroperitoneal injections like the</p> <p>9 treated animals did?</p> <p>10 A. I was not able to find in this</p> <p>11 study whether or not the four different time</p> <p>12 points received a control injection or not.</p> <p>13 Q. But would you agree, if we look</p> <p>14 at page 84 of your chart -- I'm sorry --</p> <p>15 page 83 of your report, Koehn 2020 -- or</p> <p>16 actually, in your description of Koehn 2020,</p> <p>17 it was given the highest score, a 2, for</p> <p>18 controls?</p> <p>19 A. Yeah, I would amend that.</p> <p>20 That's a mistake.</p> <p>21 Q. Okay.</p> <p>22 A. Now knowing that, I would give</p> <p>23 it a zero.</p> <p>24 Q. Do you think it's proper for</p> <p>25 study authors to use untreated controls?</p>
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<p>1 that to be an appropriate control would need</p> <p>2 to be replicated in the same type of gavage</p> <p>3 administration in a control, right?</p> <p>4 MS. HUNT: Object to form.</p> <p>5 You can answer.</p> <p>6 THE WITNESS: Yes.</p> <p>7 QUESTIONS BY MR. PADGETT:</p> <p>8 Q. Okay.</p> <p>9 A. But I would like to point</p> <p>10 something out. So this study is not</p> <p>11 completely at issue because they have</p> <p>12 multiple time points, they have temporal</p> <p>13 data, which can be used as controls. So</p> <p>14 later time points can be used as their own</p> <p>15 controls.</p> <p>16 So fortunately for these</p> <p>17 authors, the ten-hour, 23 -- ten-hour time</p> <p>18 point can be used as control for the 20, 30</p> <p>19 40, 50 hour.</p> <p>20 So the zero time point that's</p> <p>21 not controlled for is unreliable because they</p> <p>22 don't have a control gavage time point. But</p> <p>23 the other time point can be used as a control</p> <p>24 for the subsequent time points.</p> <p>25 Q. I'm going to hand you what's</p>	<p>1 MS. HUNT: Object to -- sorry.</p> <p>2 Are you done?</p> <p>3 MR. PADGETT: Yes.</p> <p>4 MS. HUNT: Object to form.</p> <p>5 You can answer.</p> <p>6 THE WITNESS: In general,</p> <p>7 researchers should use vehicle-treated</p> <p>8 controls for their studies to have the</p> <p>9 best controls. That's why I have it</p> <p>10 as a scorable criterion.</p> <p>11 In the Koehn, et al., study,</p> <p>12 there's aspects of the study that are</p> <p>13 controlled. So for some of their --</p> <p>14 some of their comparisons where they</p> <p>15 have cannulated dams in some of their</p> <p>16 pups, they have -- they have controls</p> <p>17 there.</p> <p>18 But it's true for the</p> <p>19 acetaminophen conditions with the</p> <p>20 subchronic four-dose treatment, it</p> <p>21 does not appear as though they have</p> <p>22 the vehicle control, which is, again,</p> <p>23 why I would revise the score for that</p> <p>24 particular study as well as the Beck</p> <p>25 study. It is important.</p>

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<p style="text-align: right;">Page 170</p> <p>1 (Pearson Exhibit 72 marked for 2 identification.) 3 QUESTIONS BY MR. PADGETT: 4 Q. I'm going to hand you what's 5 been marked as Exhibit 72 and ask, do you 6 recognize that document? 7 A. I do recognize this document. 8 Q. Okay. And that is the Tyl 9 article that's referenced many times in your 10 report, correct? 11 A. Yes. 12 Q. Come back to that, but I want 13 to ask you about the -- in the Koehn study 14 again. 15 If you turn to page 4 -- 16 A. Of Koehn? 17 Q. Yes. 18 At page 97 of your report, if 19 you want to look at that, you scored the 20 sample size as appropriate, with a score of 1 21 for Koehn 2020. 22 Do you disagree with that? 23 A. Koehn 2020 has a lot of 24 different comparisons. I think for some of 25 their analyses they're well-powered; for some</p>	<p style="text-align: right;">Page 172</p> <p>1 appropriate to use for a particular 2 application. 3 QUESTIONS BY MR. PADGETT: 4 Q. The results section on page 7 5 notes instances where only four animals were 6 used. 7 Do you -- do you think that is 8 a proper sample size? 9 MS. HUNT: Object to form. 10 You can answer. 11 THE WITNESS: A sample size of 12 four can be appropriate depending on 13 the study. 14 QUESTIONS BY MR. PADGETT: 15 Q. Depending on the study. 16 How do you determine if there's 17 a sufficient number of pregnant animals to 18 ensure that an adequate number of offspring 19 are produced for developmental 20 neurotoxicology evaluation? 21 MS. HUNT: Object to form. 22 You can answer. 23 THE WITNESS: It's a 24 case-by-case study. It depends -- it 25 really depends on what you're doing,</p>
<p style="text-align: right;">Page 171</p> <p>1 of their analyses they have low sample size. 2 It's a bit of a -- it's a bit of a mixture. 3 Q. And if you turn to page 4 of 4 Koehn under animals, it says, "Animal numbers 5 were" -- it's kind of about the middle of the 6 paragraph. "Animal numbers were based on 7 previous experiments of such" -- "previous 8 experience of such experiments and where the 9 minimum number required to detect a 10 significance between groups at P less than 11 .05." 12 Do you see that? 13 A. I see it. 14 Q. Okay. Is that a scientifically 15 appropriate method for determining sufficient 16 sample size? 17 A. It can be. 18 Q. And at times it cannot be, 19 correct? 20 MS. HUNT: Object to form. 21 You can answer. 22 THE WITNESS: When designing 23 and conducting research, researchers 24 can rely on their experience in 25 understanding how many animals are</p>	<p style="text-align: right;">Page 173</p> <p>1 what the parameters are, if it's 2 regulatory, if it's nonregulatory, if 3 it's exploratory, if it's 4 confirmatory. It very much depends. 5 QUESTIONS BY MR. PADGETT: 6 Q. Generally, should an a priori 7 power analysis be used to determine the 8 animal -- the number of animals needed to see 9 an effect of a certain size? 10 A. I would refer back to my 11 previous answer. It depends on if it's an 12 exploratory study or if it's a confirmatory 13 study, if it's a regulatory study, if it's -- 14 if it's exploratory empirical study. 15 Q. You did an a priori analysis as 16 a part of the Baker 2023 study, right? 17 A. Can you state that question 18 again? I'm sorry. 19 Q. You did an a priori analysis to 20 determine the number of animals needed as 21 part of your Baker 2023 study, right? 22 A. I'm trying to recall. For the 23 IACUC approval we did, yes. 24 Q. Okay. One of the things you 25 discuss out of the Koehn 2020 study -- and</p>

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<p style="text-align: right;">Page 174</p> <p>1 this is on page 96 of your summary -- of your</p> <p>2 report where you summarize it -- is that</p> <p>3 there was an increase of AFP levels in</p> <p>4 treated dams.</p> <p>5 What again are -- what again is</p> <p>6 AFP?</p> <p>7 A. I believe it's</p> <p>8 alpha-fetoprotein --</p> <p>9 Q. Okay.</p> <p>10 A. -- if I recall correctly.</p> <p>11 Q. Given that -- and you point</p> <p>12 that out in your report, right?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And given that -- if you</p> <p>15 look at Figure 8 of Koehn, "AFP data are</p> <p>16 based on a number of 1 or 2 per group" --</p> <p>17 would you agree the differences could</p> <p>18 possibly be due to individual variability?</p> <p>19 MS. HUNT: Can you give me a</p> <p>20 page number for Figure 8?</p> <p>21 Sorry, it's a long paper.</p> <p>22 THE WITNESS: Yeah, it is.</p> <p>23 MR. PADGETT: Yeah, it is long.</p> <p>24 That would be page 22.</p> <p>25 MS. HUNT: Thank you.</p>	<p style="text-align: right;">Page 176</p> <p>1 the placental permeability measures showed</p> <p>2 that placental transfer was potentially</p> <p>3 affected by APAP treatment and demonstrated</p> <p>4 increased levels of AFP detected in blood</p> <p>5 plasma of dams treated with APAP, indicative</p> <p>6 of elevated fetal-to maternal leakiness of</p> <p>7 placenta," end quote.</p> <p>8 Did I read that right?</p> <p>9 A. You did read that right.</p> <p>10 Q. Okay.</p> <p>11 A. But I did not say it's</p> <p>12 sufficient.</p> <p>13 And additionally, the exhibit</p> <p>14 that you gave me before, which is -- now I've</p> <p>15 lost it because my pile is huge here. But</p> <p>16 the Tyl, et al., or Tyl, et al., talks about</p> <p>17 there's biological significance and there's</p> <p>18 statistical significance.</p> <p>19 The biological significance of</p> <p>20 this might be meaningful, even if it's not</p> <p>21 statistically significant. So it might be</p> <p>22 worth mentioning, even if it's not</p> <p>23 statistically significant.</p> <p>24 Q. Can you turn to page 33 of the</p> <p>25 Koehn study?</p>
<p style="text-align: right;">Page 175</p> <p>1 THE WITNESS: So you said that</p> <p>2 in my report I said -- I just -- from</p> <p>3 what I read from my report, I just say</p> <p>4 that they display full-length gels for</p> <p>5 AFP Western Blots. I don't say AFP is</p> <p>6 elevated.</p> <p>7 QUESTIONS BY MR. PADGETT:</p> <p>8 Q. I believe it's page 96 of your</p> <p>9 summary.</p> <p>10 A. I don't think I drew the</p> <p>11 conclusion that AFP was significantly changed</p> <p>12 anywhere in my report.</p> <p>13 I refer to the fact that they</p> <p>14 give the full-length gels, which I appreciate</p> <p>15 because it shows they're transparent.</p> <p>16 And then I also say that some</p> <p>17 analyses are qualitative, for example, the</p> <p>18 permeability metrics and the</p> <p>19 alpha-fetoprotein Western Blot. So I'm</p> <p>20 saying that they're not including statistics</p> <p>21 for that, which is a criticism.</p> <p>22 Q. I'm sorry, it's on page 95,</p> <p>23 going over to 96.</p> <p>24 A. Okay.</p> <p>25 Q. You state, quote, "Results from</p>	<p style="text-align: right;">Page 177</p> <p>1 A. 33. I'm there.</p> <p>2 Q. You see how it's -- the</p> <p>3 italicized is the author response, and the</p> <p>4 non-italicized are comments from reviews,</p> <p>5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Let me ask you this.</p> <p>8 Are you familiar with the</p> <p>9 F1000Research journal platform?</p> <p>10 A. A little bit.</p> <p>11 Q. Have you ever -- have you ever</p> <p>12 submitted any study articles for publication</p> <p>13 to F1000Research?</p> <p>14 A. I have not.</p> <p>15 Q. Have you ever submitted any</p> <p>16 study articles to a journal platform that</p> <p>17 publishes the study before peer review is</p> <p>18 conducted?</p> <p>19 A. I have not.</p> <p>20 Q. Would you submit a study</p> <p>21 article done at Columbia University to a</p> <p>22 re -- a journal platform that publishes</p> <p>23 article prior to peer review?</p> <p>24 MS. HUNT: Objection. Scope.</p> <p>25 You can answer.</p>

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<p>1 THE WITNESS: I would consider</p> <p>2 it. I think it's an interesting</p> <p>3 model.</p> <p>4 QUESTIONS BY MR. PADGETT:</p> <p>5 Q. What's a -- can you explain to</p> <p>6 me what's a positive control?</p> <p>7 A. Generally speaking, a positive</p> <p>8 control is using something to elicit a</p> <p>9 response in your system, that you know would</p> <p>10 elicit a response in your system, so that you</p> <p>11 can demonstrate that you can measure what you</p> <p>12 intend to measure.</p> <p>13 Q. And you indicate on page 7 of</p> <p>14 your -- 8 of your report that the absence of</p> <p>15 a positive control data does not necessarily</p> <p>16 disqualify a study from consideration unless</p> <p>17 there's a reason to believe the experimental</p> <p>18 lab -- or experimenter or lab is not capable</p> <p>19 of reliably measuring the outcome of</p> <p>20 interest, right?</p> <p>21 A. I maintain that --</p> <p>22 Q. Yeah.</p> <p>23 A. -- opinion.</p> <p>24 Q. If you turn to Exhibit 11,</p> <p>25 which is Tyl. I'm sorry, Exhibit...</p>	<p>1 context, under GLP, like Good Laboratory</p> <p>2 Practice, pharmaceutical, risk assessment</p> <p>3 situations.</p> <p>4 If you're doing empirical</p> <p>5 research and you have laboratory scientists</p> <p>6 that have good track records and you're doing</p> <p>7 relatively straightforward assays, it's not</p> <p>8 necessarily applicable.</p> <p>9 Q. Do you agree that Dr. -- that</p> <p>10 Dr. Tyl's article here that you've quoted</p> <p>11 from and relied on extensively in your report</p> <p>12 is actually focused more on regulatory</p> <p>13 develop -- neuro -- neurotoxicology studies</p> <p>14 and --</p> <p>15 A. I think its general</p> <p>16 applicability as to -- is oftentimes to</p> <p>17 regulatory.</p> <p>18 Q. In evaluating the evidence</p> <p>19 included in your weight of evidence</p> <p>20 evaluation, you applied the same scoring</p> <p>21 system for in vivo and in vitro studies,</p> <p>22 right?</p> <p>23 A. I used the same scoring system</p> <p>24 for an ex utero and in vivo, yes.</p> <p>25 Q. Are you distinguishing between</p>
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<p>1 A. Yeah. 72?</p> <p>2 Q. 72?</p> <p>3 Page 353 under Section 3.12,</p> <p>4 Positive Controls.</p> <p>5 Do you see that?</p> <p>6 A. 353 or 252? I'm sorry?</p> <p>7 Q. 353.</p> <p>8 It's immediately under 3.12,</p> <p>9 Positive Controls. Dr. Tyl states that "a</p> <p>10 critical element in the review of a DNT study</p> <p>11 is availability of adequate positive control</p> <p>12 data."</p> <p>13 Do you agree with that</p> <p>14 statement?</p> <p>15 A. I agree -- I would agree with</p> <p>16 the statement under certain contexts.</p> <p>17 Q. And what -- under what context</p> <p>18 would you disagree with Dr. Tyl's statement</p> <p>19 there?</p> <p>20 A. I think it would be easier for</p> <p>21 me to agree with it on -- it would be easier</p> <p>22 for me to do the opposite, to do the inverse</p> <p>23 of that.</p> <p>24 I think having positive control</p> <p>25 data is incredibly important under regulatory</p>	<p>1 in vitro and ex utero?</p> <p>2 A. Ex utero.</p> <p>3 I -- I distinguish them because</p> <p>4 there's -- they're -- I'm -- in an umbrella</p> <p>5 sense, they're -- they can be lumped</p> <p>6 together, but there's also some distinctions</p> <p>7 between them.</p> <p>8 Q. Would you agree that the con --</p> <p>9 first of all, what is publication bias?</p> <p>10 A. Publication bias is a</p> <p>11 phenomenon whereby people could selectively</p> <p>12 publish things that only support -- or could</p> <p>13 fail to publish things that don't fit their</p> <p>14 idea of what they think should happen.</p> <p>15 So null findings don't get</p> <p>16 published, or only null findings get</p> <p>17 published, for instance.</p> <p>18 Q. Would you agree that the</p> <p>19 concept of publication bias weighs in favor</p> <p>20 of published studies ending up on the plus</p> <p>21 side of your scale in your weight of</p> <p>22 analysis -- weight of evidence evaluation</p> <p>23 done here?</p> <p>24 MS. HUNT: Object to form.</p> <p>25 You can answer.</p>

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<p>1 THE WITNESS: I would not</p> <p>2 necessarily agree with that. There</p> <p>3 are null studies that are in my weight</p> <p>4 of evidence analysis.</p> <p>5 QUESTIONS BY MR. PADGETT:</p> <p>6 Q. Is there any other null study</p> <p>7 other than Saad 2016 in your weight of</p> <p>8 evidence analysis?</p> <p>9 A. Yes.</p> <p>10 Q. What one or ones?</p> <p>11 A. They are there. In the in --</p> <p>12 the in vivo, ex utero, there are null</p> <p>13 studies. There are multiple -- there's more</p> <p>14 than -- yeah, let me find them.</p> <p>15 Do I need to find them, or do</p> <p>16 you want to --</p> <p>17 Q. Are there any in vivo studies</p> <p>18 listed at pages 83 or 81 in your -- those two</p> <p>19 tables of mouse and rat studies --</p> <p>20 A. Yes.</p> <p>21 Q. -- other than Saad that are --</p> <p>22 that were null?</p> <p>23 MS. HUNT: Object to form.</p> <p>24 You can answer.</p> <p>25 THE WITNESS: Yes, Philippot,</p>	<p>1 of the question.</p> <p>2 You can answer.</p> <p>3 THE WITNESS: We've been doing</p> <p>4 plenty of hypotheticals here today,</p> <p>5 so...</p> <p>6 MR. PADGETT: I'm at a breaking</p> <p>7 point if you want to take the lunch.</p> <p>8 THE WITNESS: Lunchtime?</p> <p>9 VIDEOGRAPHER: The time right</p> <p>10 now is 12:36 p.m., and we're off the</p> <p>11 record.</p> <p>12 (Off the record at 12:36 p.m.)</p> <p>13 VIDEOGRAPHER: The time right</p> <p>14 now is 1:35 p.m., and we're back on</p> <p>15 the record.</p> <p>16 QUESTIONS BY MR. PADGETT:</p> <p>17 Q. Dr. Pearson, do you believe</p> <p>18 that postnatal -- do you believe that use of</p> <p>19 APAP in human offspring after delivery is a</p> <p>20 risk factor for ASD or ADHD?</p> <p>21 A. I haven't evaluated the</p> <p>22 comprehensive weight of evidence to determine</p> <p>23 whether postnatal use of acetaminophen use is</p> <p>24 associated with ASD and ADHD, so I'm not able</p> <p>25 to determine that.</p>
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<p>1 et al., 2021.</p> <p>2 QUESTIONS BY MR. PADGETT:</p> <p>3 Q. Okay.</p> <p>4 A. I don't believe there were any</p> <p>5 in the rat.</p> <p>6 So to elaborate, I think</p> <p>7 publication bias can go -- can work in both</p> <p>8 directions. There's an interest --</p> <p>9 publication bias could work in the interest</p> <p>10 of both perspectives.</p> <p>11 Q. When you say that, do you mean</p> <p>12 that there's -- what do you mean by "both</p> <p>13 directions"?</p> <p>14 A. "Both directions" meaning that</p> <p>15 there's people who think that -- in this</p> <p>16 particular case that acetaminophen is a</p> <p>17 developmental neurotoxicant that can lead to</p> <p>18 these health outcomes. There's people that</p> <p>19 believe that that's not the case.</p> <p>20 So people could perform studies</p> <p>21 and then only study those -- only publish</p> <p>22 studies that support that perspective.</p> <p>23 Q. You're speculating on that</p> <p>24 right now, right?</p> <p>25 MS. HUNT: Object to the form</p>	<p>1 From a biological plausibility,</p> <p>2 I think it's possible.</p> <p>3 Q. You just said it's possible,</p> <p>4 but as you sit here today, no conclusive</p> <p>5 belief on whether postnatal use of APAP in</p> <p>6 offspring after delivery is a risk factor for</p> <p>7 ASD or ADHD?</p> <p>8 A. As I mentioned, I haven't done</p> <p>9 a full weight of evidence analysis on that</p> <p>10 particular topic, so I can't say for certain.</p> <p>11 But as I mentioned, given</p> <p>12 the mechanism of damage of acetaminophen on</p> <p>13 neurological systems, and given that the</p> <p>14 brain isn't fully developed in the postnatal</p> <p>15 period, I believe it's plausible.</p> <p>16 Q. You said possible first, now</p> <p>17 it's plausible?</p> <p>18 MS. HUNT: Object to form.</p> <p>19 You can answer.</p> <p>20 THE WITNESS: I think possible</p> <p>21 and plausible are within the same</p> <p>22 realm of -- can be used</p> <p>23 interchangeably.</p> <p>24 QUESTIONS BY MR. PADGETT:</p> <p>25 Q. Okay. Do you think a child's</p>

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<p style="text-align: right;">Page 186</p> <p>1 use of APAP after delivery is a confounder</p> <p>2 for human studies assessing in utero</p> <p>3 exposure?</p> <p>4 A. You're asking me whether I</p> <p>5 think a child's use of acetaminophen in the</p> <p>6 postnatal period is a confounder?</p> <p>7 Q. Let's say perinatal period</p> <p>8 after delivery. Is that a confounder for</p> <p>9 human studies assessing in utero exposure?</p> <p>10 A. I'm not familiar enough with</p> <p>11 that to know whether that's a confounder or</p> <p>12 not.</p> <p>13 Q. Do you intend to offer opinions</p> <p>14 in this litigation that potential use of APAP</p> <p>15 in human offspring causes ADHD or ASD?</p> <p>16 MS. HUNT: Object to the form</p> <p>17 of the question.</p> <p>18 You can answer.</p> <p>19 THE WITNESS: Could you repeat</p> <p>20 the question, please?</p> <p>21 QUESTIONS BY MR. PADGETT:</p> <p>22 Q. Yes, definitely, based on what</p> <p>23 I see here.</p> <p>24 Do you intend to offer opinions</p> <p>25 in this litigation that postnatal use of APAP</p>	<p style="text-align: right;">Page 188</p> <p>1 litigation that postnatal use of APAP in</p> <p>2 human offspring causes ADHD or ASD?</p> <p>3 A. Respectfully, my understanding</p> <p>4 is, is that this point of the phase I of this</p> <p>5 litigation is general causality about</p> <p>6 prenatal exposures to acetaminophen and ASD</p> <p>7 and ADHD. And my expert testimony has to do</p> <p>8 with the preclinical literature and the</p> <p>9 weight of evidence that I performed pursuant</p> <p>10 to that.</p> <p>11 You're asking me about</p> <p>12 something completely different, and I've not</p> <p>13 reviewed the literature, nor have I been</p> <p>14 offered any documents that I can review with</p> <p>15 respect to that.</p> <p>16 Q. And my question is, in light of</p> <p>17 what you just said, do you agree at this</p> <p>18 point in time you do not intend to offer</p> <p>19 opinions that postnatal use of APAP in human</p> <p>20 offspring causes ADHD or ASD in this</p> <p>21 litigation?</p> <p>22 A. As I said previously, if I'm</p> <p>23 given the opportunity and other information</p> <p>24 and other literature, I would reserve the</p> <p>25 opportunity to offer an opinion at such time.</p>
<p style="text-align: right;">Page 187</p> <p>1 in human offspring causes ADHD or ASD?</p> <p>2 A. I reserve the right to offer</p> <p>3 opinions based on any evidence that I'm --</p> <p>4 that's made available to me that I can</p> <p>5 review.</p> <p>6 Q. As you sit here today,</p> <p>7 recognizing your reservation based on</p> <p>8 additional evidence, do you -- as you sit</p> <p>9 here today, do you intend to offer opinions</p> <p>10 in this litigation that postnatal use of APAP</p> <p>11 in human offspring causes ADHD or ASD?</p> <p>12 A. This is outside of the scope of</p> <p>13 my mandate. The mandate that I have been</p> <p>14 given for this particular proceeding is to</p> <p>15 evaluate the preclinical evidence as to</p> <p>16 whether acetaminophen is associated with the</p> <p>17 particular health outcomes. So I haven't</p> <p>18 performed a weight of evidence analysis on</p> <p>19 postnatal human exposures to acetaminophen</p> <p>20 and those health outcomes.</p> <p>21 Q. In light of the fact that you</p> <p>22 have not performed the weight of evidence</p> <p>23 analysis of postnatal use of APAP in human</p> <p>24 offspring, is it fair to say you do not</p> <p>25 intend to offer opinions at this time in this</p>	<p style="text-align: right;">Page 189</p> <p>1 Q. I understand your reservation.</p> <p>2 But as you sit here today, do</p> <p>3 you intend to offer an opinion on postnatal</p> <p>4 use of APAP in human offspring as to whether</p> <p>5 it causes ADHD or ASD?</p> <p>6 MS. HUNT: Objection. Asked</p> <p>7 and answered.</p> <p>8 QUESTIONS BY MR. PADGETT:</p> <p>9 Q. As you sit here today.</p> <p>10 A. I do not wish to give an</p> <p>11 opinion on that right now because, as I said,</p> <p>12 that's outside of the scope of my expert</p> <p>13 testimony today.</p> <p>14 Q. And you have no intent to give</p> <p>15 that opinion right now?</p> <p>16 A. I have been not -- I have not</p> <p>17 been asked to give an opinion on that to</p> <p>18 date.</p> <p>19 If I am asked to give an</p> <p>20 opinion on that, I reserve the right to give</p> <p>21 an opinion on that, given sufficient time and</p> <p>22 literature.</p> <p>23 Q. We talked earlier about the</p> <p>24 Koehn 2020 study, and that involved use of a</p> <p>25 radiolabeled drug, right?</p>

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<p>1 A. I believe Koehn used a 2 tritiated acetaminophen, if I recall 3 correctly. 4 Q. Is that a radiolabeled? 5 A. It is. 6 Q. Okay. The study -- did the 7 study provide any information on -- would you 8 agree that the levels of acetaminophen in 9 that study are at a single point in time? 10 MS. HUNT: Object to the form 11 of the question. 12 You can answer. 13 THE WITNESS: You're asking me 14 whether in Koehn that the level of 15 acetaminophen is at a single point in 16 time? 17 QUESTIONS BY MR. PADGETT: 18 Q. Is measured at a single point 19 in time. 20 A. I think you would have to 21 clarify your question a little bit. 22 The level of acetaminophen is 23 measured in different compartments in the 24 Koehn, et al., study. 25 Q. At individual points in time.</p>	<p>1 study. 2 Q. Are you currently looking at 3 the 20 -- Koehn 2019 or Koehn 2020? 4 A. I -- in front of me I have 5 Koehn 2020. 6 (Pearson Exhibit 76 marked for 7 identification.) 8 QUESTIONS BY MR. PADGETT: 9 Q. I'm going to hand you -- I'm 10 going to hand you what's been marked as 11 Exhibit 76. 12 Is this the Koehn 2019 study? 13 A. This is Koehn 2019, yes. 14 Q. Okay. And did this use 15 radiolabeled acetaminophen? 16 It's right there in the 17 abstract, radiolabeled drugs, right? 18 A. One point of clarification. I 19 don't know that I used this study in my 20 weight of evidence analysis. I think I used 21 this study in my background. 22 Q. Okay. 23 A. I just want to make sure that's 24 on the record. 25 So when you referred to it</p>
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<p>1 In other words, the study 2 doesn't provide information on how quickly 3 those levels would change over time, right? 4 A. Is there -- is there something 5 you can point me to in the study that you're 6 referring to? Because I'm not necessarily 7 following what you're getting at. 8 Q. You mentioned that it looked at 9 different areas of the brain. And my 10 question is, when they look at the levels, 11 those are for a single point in time for 12 whatever area they're looking at. It doesn't 13 assess across time in terms of those levels. 14 That's my question. 15 A. So in the Koehn, et al., study, 16 they looked at gene expression in the brain 17 and the placenta. 18 You're saying that I testified 19 to something about different regions of the 20 brain. I'm not sure to what you're referring 21 to that I stated. 22 Q. Are you looking at 2020 or 23 2019? 24 A. I would pose the question to 25 you on -- you're the one who brought up the</p>	<p>1 earlier, it threw me off because this was not 2 in my weight of evidence. So let me just 3 make sure we're on the same page. 4 So in the abstract, you're 5 indicating that they -- they say that they 6 use a radiolabeled drug. 7 It does say that they used 8 radiolabeled substances in rats. 9 Q. Okay. And for the doses given, 10 my question is, did they assess the levels 11 and whether they changed over time in Koehn 12 2019? 13 MS. HUNT: Object to form. 14 You can answer. 15 THE WITNESS: Let me take a 16 moment and look at their figures. 17 They did. Figure 6. 18 QUESTIONS BY MR. PADGETT: 19 Q. Figure 6? 20 A. Yes, on page 14. Bottom 21 panels, acute administration and chronic 22 administration. 23 Q. I'm talking for individual 24 doses. Did they measure the levels for an 25 individual dose at different points in time</p>

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<p>1 over time? That's my question.</p> <p>2 A. Yes, that's what's being</p> <p>3 measured here. They're measuring</p> <p>4 deprecations per minute, which is what the</p> <p>5 radiolabeled gives you.</p> <p>6 Q. Okay.</p> <p>7 A. If you put tritium onto a drug,</p> <p>8 it decays. It's what a radioactive element</p> <p>9 does. It -- the protons within the nucleus</p> <p>10 of that decay. And if you put it inside --</p> <p>11 inside of a counter, it measures the</p> <p>12 deprecations. And so this is a measurement</p> <p>13 of how much a drug -- drug is in that sample.</p> <p>14 Q. And it was over the course of</p> <p>15 one minute, did you say?</p> <p>16 A. No. The course of, it looks</p> <p>17 like, 150 minutes.</p> <p>18 Q. Okay. Was there a comparison</p> <p>19 between the levels examined there in fetus</p> <p>20 versus pregnant females?</p> <p>21 A. Yes.</p> <p>22 Q. It wasn't adults that were</p> <p>23 nonpregnant females?</p> <p>24 MS. HUNT: Object to the form</p> <p>25 of the question.</p>	<p>1 Q. And we talked about</p> <p>2 F1000Research previously, but based on the</p> <p>3 front cover page where it says "first</p> <p>4 published" --</p> <p>5 A. Yes.</p> <p>6 Q. -- August 7, 2019, and latest</p> <p>7 published, August 7, 2019, would you agree</p> <p>8 that there were no revisions made to this</p> <p>9 article after initial publication without</p> <p>10 peer review?</p> <p>11 MS. HUNT: Object to form.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: I wouldn't know</p> <p>14 because I didn't download this. I</p> <p>15 haven't looked.</p> <p>16 QUESTIONS BY MR. PADGETT:</p> <p>17 Q. This Koehn 2019 used injection</p> <p>18 method, right?</p> <p>19 MS. HUNT: Object to form.</p> <p>20 You can answer.</p> <p>21 QUESTIONS BY MR. PADGETT:</p> <p>22 Q. IP injection?</p> <p>23 A. I would have to look at their</p> <p>24 methods briefly to recall.</p> <p>25 It says on page 5, in all</p>
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<p>1 You can answer.</p> <p>2 THE WITNESS: My initial answer</p> <p>3 was correct.</p> <p>4 QUESTIONS BY MR. PADGETT:</p> <p>5 Q. Okay. And I'm looking at</p> <p>6 page 8, table...</p> <p>7 A. Figure 6 on the different lines</p> <p>8 show the dam versus the fetus.</p> <p>9 Q. And I'm looking at page 8,</p> <p>10 Table 5. That's what I'm asking about, to be</p> <p>11 clear.</p> <p>12 And I guess I'm specifically</p> <p>13 looking at adults or nonpregnant females and</p> <p>14 littermates of both sexes were included in</p> <p>15 the E19 or P4 age groups.</p> <p>16 The comparison there was made</p> <p>17 between the offspring and nonpregnant</p> <p>18 females, right?</p> <p>19 A. That appears to be between</p> <p>20 offspring and nonpregnant animals.</p> <p>21 Q. Okay.</p> <p>22 A. But as I mentioned in</p> <p>23 Figure 4 -- or Figure -- what were we looking</p> <p>24 for? -- Figure 6, that's between the dam and</p> <p>25 the maternal plasma versus the fetal plasma.</p>	<p>1 experiments involving postnatal animals,</p> <p>2 injections were at IP. In pregnant animals,</p> <p>3 radiolabeled marker was given intravenously.</p> <p>4 Fetal animals were individually injected IP</p> <p>5 while still in the intrauterine horn and --</p> <p>6 the uterine horn. And so a variety of</p> <p>7 injection --</p> <p>8 Q. Okay.</p> <p>9 A. -- routes.</p> <p>10 Q. Do in vitro studies capture the</p> <p>11 inherent complexity of organ systems?</p> <p>12 MS. HUNT: Object to form.</p> <p>13 You can answer.</p> <p>14 QUESTIONS BY MR. PADGETT:</p> <p>15 Q. In an animal?</p> <p>16 A. Some in vitro systems can</p> <p>17 capture some aspects of organ systems, but</p> <p>18 they cannot -- they have limitations in terms</p> <p>19 of capturing multi-organ systems in the</p> <p>20 entirety of an entire organism.</p> <p>21 Q. And they cannot account for</p> <p>22 interactions between cell and biochemical</p> <p>23 processes that occur in a living animal,</p> <p>24 right?</p> <p>25 A. I would not necessarily agree</p>

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<p>1 with that statement.</p> <p>2 Q. Would you agree that they</p> <p>3 cannot account for all of the interactions</p> <p>4 between cell and biochemical processes that</p> <p>5 occur in a living animal?</p> <p>6 A. In vitro systems cannot account</p> <p>7 for all cellular and biochemical interactions</p> <p>8 of an intact organism, that is true.</p> <p>9 Q. And they do not have</p> <p>10 absorption, distribution, metabolism or</p> <p>11 excretion processes in place, right?</p> <p>12 A. They can have -- they can have</p> <p>13 all of those processes.</p> <p>14 To elaborate, so in vitro</p> <p>15 systems can include each of those processes.</p> <p>16 Q. Can include all four at the</p> <p>17 same time?</p> <p>18 A. So organ-on-a-chip systems.</p> <p>19 Transwell systems. There are advanced in</p> <p>20 vitro systems that can incorporate hepatic</p> <p>21 kidney-type systems and multi-organ-on-a-chip</p> <p>22 systems that -- that can capture a lot of the</p> <p>23 ADME properties.</p> <p>24 Q. And not to the -- would you</p> <p>25 agree not to the same extent as a living</p>	<p>1 There is the -- the only</p> <p>2 paragraph of text there, as opposed to the</p> <p>3 tables and charts, this -- that paragraph</p> <p>4 relates to Comparative Toxicogenomics</p> <p>5 Database.</p> <p>6 Is that right?</p> <p>7 A. Yes.</p> <p>8 Q. But you're also -- you also</p> <p>9 note that the relevance -- reliability is low</p> <p>10 to medium for the in silico line of evidence,</p> <p>11 right?</p> <p>12 A. That's correct.</p> <p>13 Q. The relevance is low, and the</p> <p>14 weight assigned is low, right?</p> <p>15 A. That's what it says.</p> <p>16 Q. Okay. And that is because, as</p> <p>17 you note here, this type of high through --</p> <p>18 quote, "high through-put data have several</p> <p>19 major limitations in modeling human health</p> <p>20 and disease," end quote.</p> <p>21 Is that -- did I read that</p> <p>22 correctly on page 126?</p> <p>23 A. You read that correctly.</p> <p>24 Q. Okay. And mod -- with regard</p> <p>25 to modeling human health and disease, the</p>
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<p>1 organism?</p> <p>2 A. In vitro systems cannot capture</p> <p>3 every aspect of a full, complete organism.</p> <p>4 Q. And you discuss in your report</p> <p>5 in silico data, right?</p> <p>6 A. I discuss in silico data, yes.</p> <p>7 Q. And that has major limitations</p> <p>8 in modeling human health and disease,</p> <p>9 correct?</p> <p>10 MS. HUNT: Object to form.</p> <p>11 You can answer.</p> <p>12 THE WITNESS: In silico systems</p> <p>13 can have certain limitations.</p> <p>14 QUESTIONS BY MR. PADGETT:</p> <p>15 Q. Would you characterize them as</p> <p>16 major limitations?</p> <p>17 MS. HUNT: Object to form.</p> <p>18 You can answer.</p> <p>19 THE WITNESS: It would depend</p> <p>20 on the application. They can have --</p> <p>21 on the contrary, they can have major</p> <p>22 strengths.</p> <p>23 QUESTIONS BY MR. PADGETT:</p> <p>24 Q. If you turn to page 126 of your</p> <p>25 report.</p>	<p>1 major limitations would include ASD and ADHD,</p> <p>2 right?</p> <p>3 MS. HUNT: Object to the form</p> <p>4 of the question.</p> <p>5 You can answer.</p> <p>6 THE WITNESS: ASD and ADHD</p> <p>7 are components of human health and</p> <p>8 disease.</p> <p>9 QUESTIONS BY MR. PADGETT:</p> <p>10 Q. You discussed early in -- well,</p> <p>11 I guess about page 124, you talk about that</p> <p>12 APAP has been tested in 970 assays in</p> <p>13 something known as the EPA ToxCast dashboard?</p> <p>14 A. Yes.</p> <p>15 Q. And of those 979 assays you</p> <p>16 identify here on pages 124 to 125, four that</p> <p>17 showed active calls; is that right?</p> <p>18 A. That's correct.</p> <p>19 Q. Can you describe specifically</p> <p>20 how these four active calls support a</p> <p>21 specific finding of acetaminophen as a</p> <p>22 causal -- that acetaminophen can cause ASD or</p> <p>23 ADHD?</p> <p>24 A. On a weight of evidence</p> <p>25 analysis, you don't rely on one level of</p>

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<p>1 analysis to -- or level of evidence to</p> <p>2 support a causal framework. You rely on the</p> <p>3 totality and multiple levels of evidence.</p> <p>4 So to more directly answer your</p> <p>5 question, I wouldn't rely just on this single</p> <p>6 data to do that. But -- yeah.</p> <p>7 But in the -- in the full</p> <p>8 weight of evidence analysis, these kinds of</p> <p>9 results can be supportive in that these</p> <p>10 assays support the specificity of the types</p> <p>11 of effects.</p> <p>12 So the first assay where you</p> <p>13 have activity and relatively low -- rather</p> <p>14 high sensitivity where you have a low AC50 is</p> <p>15 androgen receptor. And we know that</p> <p>16 acetaminophen has activity on androgen</p> <p>17 receptor, so that makes intuitive sense from</p> <p>18 a toxicological perspective.</p> <p>19 The second assay is a nuclear</p> <p>20 hormone receptor, a progesterone receptor.</p> <p>21 The third one, in HepaRG cells,</p> <p>22 which are hepatocytes, it makes sense that</p> <p>23 you have CYP450 activity there.</p> <p>24 And the last one is SOX</p> <p>25 activity, which is essentially a</p>	<p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. Okay. I'm going to hand you</p> <p>3 what's been marked as Exhibit 74.</p> <p>4 Is this --</p> <p>5 MS. HUNT: Can I have a copy?</p> <p>6 MR. PADGETT: Oh, I'm sorry.</p> <p>7 MS. HUNT: Thank you.</p> <p>8 QUESTIONS BY MR. PADGETT:</p> <p>9 Q. And is exhibit -- which number</p> <p>10 is that, please?</p> <p>11 A. 74.</p> <p>12 Q. Is Exhibit 74 going to be</p> <p>13 introductory material about the EPA ToxCast</p> <p>14 database, followed by the specific</p> <p>15 information on acetaminophen discussed in</p> <p>16 your report there at pages 124 to 25?</p> <p>17 MS. HUNT: Object to the form</p> <p>18 of the question.</p> <p>19 You can answer.</p> <p>20 THE WITNESS: Are you asking is</p> <p>21 this specific information discussed in</p> <p>22 my report?</p> <p>23 QUESTIONS BY MR. PADGETT:</p> <p>24 Q. No. Would you agree that that</p> <p>25 is -- does that look familiar to you as --</p>
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<p>1 transcription factor that's involved in</p> <p>2 development. So in that sense, the</p> <p>3 development's maybe not surprising given the</p> <p>4 neurodevelopmental activity that we're</p> <p>5 interested in.</p> <p>6 Q. Did you actually go into the</p> <p>7 EPA ToxCast dashboard and review the data</p> <p>8 that these four calls -- assays were</p> <p>9 reproduced in your report?</p> <p>10 MS. HUNT: Object to form.</p> <p>11 You can answer.</p> <p>12 THE WITNESS: Are you asking</p> <p>13 whether I read more about these</p> <p>14 specific assays?</p> <p>15 QUESTIONS BY MR. PADGETT:</p> <p>16 Q. Strike that.</p> <p>17 Did you go into the EPA ToxCast</p> <p>18 database and look at the information on that</p> <p>19 database that's reflected in your report at</p> <p>20 pages 124 to 25?</p> <p>21 MS. HUNT: Object to form.</p> <p>22 You can answer.</p> <p>23 THE WITNESS: Yes.</p> <p>24 (Pearson Exhibit 74 marked for</p> <p>25 identification.)</p>	<p>1 from EPA ToxCast database? At least the</p> <p>2 materials on acetaminophen?</p> <p>3 A. Yes, it does.</p> <p>4 Q. And the ToxCast program has</p> <p>5 acknowledged that false positive and negative</p> <p>6 hit calls are possible using their automated</p> <p>7 methods, and so they've added a processing</p> <p>8 step to assign flags or warnings about the</p> <p>9 data.</p> <p>10 Do you understand that?</p> <p>11 A. I do.</p> <p>12 Q. Okay. Are there any flags or</p> <p>13 warnings referenced in the data on pages 124</p> <p>14 to 25 of your expert report with regard to</p> <p>15 those four assays?</p> <p>16 A. There are no flags on my expert</p> <p>17 report.</p> <p>18 Q. Did you understand that the</p> <p>19 warnings -- do the warnings limit the</p> <p>20 conclusions that can be drawn from the</p> <p>21 results?</p> <p>22 A. If the ToxCast algorithms flag</p> <p>23 a dose response, then it can trigger further</p> <p>24 follow-up by the computational toxicologist</p> <p>25 at the EPA to determine whether</p>

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<p>1 the curve-fitting algorithms need to be 2 refit, whether the assay performed well, or 3 whether the assay data are unreliable. 4 Q. You state there -- it's on 5 page 124 of your report -- that the ToxCast 6 dashboard shows APAP has potent activity for 7 androgen receptor. 8 Is that -- did I read that 9 right? 10 A. Yes. 11 Q. Did you review all of the 12 results from the androgen receptor assays and 13 models in the ToxCast -- EPA ToxCast 14 database? 15 MS. HUNT: Object to the form 16 of the question. 17 You can answer. 18 QUESTIONS BY MR. PADGETT: 19 Q. As to acetaminophen? Sorry. 20 A. I do not remember what I looked 21 at. I believe that I did. 22 Q. Okay. So were you aware that 23 there were 14 other androgen receptor assays 24 that were represented as inactive? 25 A. There's more nuclear receptors</p>	<p>1 Q. Okay. Did you see that when 2 you were looking at the database? 3 A. I do not recall whether I saw 4 that or not. 5 Q. Okay. But this is referring to 6 an androgen receptor, correct? 7 A. This is referring to -- 8 actually, no, it's not. It's not an androgen 9 receptor. I misread that earlier. It's a 10 nucleoli antagonist. Well, as it relates to 11 the gene AR. 12 Q. I'm talking about the one on 13 the graph that we're looking at. 14 A. Yeah, it's the same one that's 15 the top one in the table, though. 16 Q. Okay. 17 A. The most potent one with the 18 AC50 of .25, which is .25 micromolar or 251 19 nanomolar. 20 Q. And would you agree that this 21 flag and the potential confounding by 22 overfitting calls into the question of 23 reliability of this hit? 24 A. It certainly requires that the 25 toxicologist at the EPA should look more at</p>
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<p>1 beyond androgen receptor. There's -- 2 Q. I'm -- 3 A. -- receptor. There's -- yeah. 4 Q. I'm asking specifically about 5 the androgen receptor assays. 6 A. I'm aware that there are other 7 androgen receptor assays -- 8 Q. Okay. 9 A. -- that are up and -- that 10 would be up and down. 11 Q. Could you turn to the graph 12 there with the date in the right-hand -- 13 bottom right corner? Says 8/1/23, 6:04 p.m. 14 And which assay is this for? 15 Is this a nuclear antagonist? 16 A. I assume you're asking about 17 the one that says UPAHCLU2OSAR TIF2 nucleoli 18 antagonist? 19 Q. Yes. 20 A. Yes. 21 Q. And that particular one has a 22 flag for hit call, and it says, "Potentially 23 confounding by overfitting. Only one 24 concentration above baseline active." 25 A. I see that.</p>	<p>1 this dose-response relationship and determine 2 whether that dose response is biologically 3 meaningful or whether one of these other 4 concentration response curves would be 5 better. 6 So the one that's fit, that 7 gives this AC50, was what they call the 8 winning model. So that's computational. 9 That's why they give that dotted line. 10 That's the winning model, and that's the log 11 AC, that one that gives this .25 AC50. 12 Q. You -- sorry, go ahead. 13 A. So I was just going to continue 14 on. 15 They give other curves. 16 They're very, very faint in here. There's a 17 hill curve, for instance, or a gain-loss 18 curve. Those would render different AC 50s. 19 And so a toxicologist, a 20 computational toxicologist, could look at 21 this and determine, you know, based on this 22 scatter plot of dose response, it might be 23 more appropriate to not trust the computer 24 and apply one of the other ones. 25 Q. You also state there on</p>

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<p>1 page 124 that it -- "the ToxCast dashboard 2 shows that APAP has potent activity for...the 3 nuclear receptor family in general," right? 4 A. Yeah, I believe I would have 5 said that because the top two most potent 6 assays are for two intended target families 7 of nuclear receptor. 8 Q. If you could look at the graph 9 with the bottom right date of 8/1/2023, 10 6:07 p.m., please. 11 A. Yes. 12 Q. And does that -- the assay for 13 binding of the human progesterone reception? 14 A. Yes. 15 Q. And that has a flag on it, 16 right? 17 A. Yes. 18 Q. And the flag says, quote, "Less 19 than 50 percent efficacy," end quote, right? 20 A. It does. 21 Q. But that's not discussed in 22 your report, correct? 23 A. It is not discussed in my 24 report. 25 Q. You also state on page 124 that</p>	<p>1 I think some of these assays 2 can have some specificity problems 3 with respect to the fact they're 4 transcription factor reporter assays, 5 so sometimes the CYP specificity can 6 overlap. So it's not surprising to me 7 to see CYP1A1 activity with respect to 8 acetaminophen. 9 QUESTIONS BY MR. PADGETT: 10 Q. So is CYP1A1 typically 11 associated with acetaminophen metabolism 12 based on the literature you've seen? 13 MS. HUNT: Objection. Form. 14 You can answer. 15 THE WITNESS: I don't know what 16 your definition of the -- of typically 17 is. I've seen literature associating 18 CYP1A1 with acetaminophen. 19 QUESTIONS BY MR. PADGETT: 20 Q. In any event, this -- if you 21 turn to the graph, 8/1/2023, for 6:09 p.m., 22 is that the graph for the CYP1A1 induction 23 reflected in your expert report? 24 A. It is reflected in my expert 25 report.</p>
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<p>1 "the ToxCast dashboard shows that APAP has 2 potent activity for...cytochrome P450 3 enzymes," correct? 4 MS. HUNT: Object to the form 5 of the question. 6 You can answer. 7 QUESTIONS BY MR. PADGETT: 8 Q. It's on page 124 of your 9 report. 10 A. Yes. 11 Q. And this was related to an 12 assay at CYP1A1 induction, correct? 13 A. Yes. 14 Q. Okay. Is the CYP1A1 enzyme -- 15 P450 enzyme typically associated with 16 acetaminophen metabolism? 17 MS. HUNT: Object to the form 18 of the question. 19 You can answer. 20 THE WITNESS: I've seen 21 literature associated with CYP1A1 and 22 APAP. I've seen it more in respect to 23 aniline to APAP. 24 I've seen also CYP1A2 in 25 acetaminophen.</p>	<p>1 Oh, I'm sorry. Is the flag 2 reflected in my expert report? 3 Q. Is the graph. 4 A. Is the graph itself or is data 5 from the graph reflected? 6 Q. Yeah, the data from the graph. 7 A. The last entry into the table 8 on page 125 comes from that. 9 Q. Okay. 10 A. Oh, no, I'm sorry, it isn't, 11 actually. No, it isn't. 12 Q. This assay, CYP1A {sic} assay, 13 is reflected in your report as one of the 14 hits that you describe, right? 15 A. No. I don't see it. 16 Q. You were talking about a CYP450 17 assay result was among the four at pages 124 18 to 125; is that right? 19 Which one of these four is it? 20 First, second, third or fourth? Is it the 21 third where it says CYP1A1? 22 A. Oh, yeah, there it is. Thank 23 you. It's that one. 24 Q. Okay. And the one that has 25 6:09 p.m. in the bottom right-hand --</p>

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<p>1 A. Yes.</p> <p>2 Q. -- corner is the graph related</p> <p>3 to that assay, right?</p> <p>4 A. It is.</p> <p>5 Q. And that graph has a flag as</p> <p>6 well, right?</p> <p>7 A. It does.</p> <p>8 Q. And the flag is, quote, "noisy</p> <p>9 data," end quote; is that correct?</p> <p>10 A. That is what it says.</p> <p>11 Q. And what does noisy data mean?</p> <p>12 A. It's referring to that the</p> <p>13 replicates are widespread.</p> <p>14 Q. Could noisy data also mean</p> <p>15 meaningless or corrupt data?</p> <p>16 A. That's not at all what that</p> <p>17 means. It just means that biology is</p> <p>18 variable. In fact, I would go on to say that</p> <p>19 this is actually beautiful data.</p> <p>20 If you look at the lower dose</p> <p>21 range, the replicates are very tight. If you</p> <p>22 go to the higher dose range, log 1.5, then</p> <p>23 the replicates become widespread. But if you</p> <p>24 actually look at the dose-response curve,</p> <p>25 it's a beautiful sigmoidal curve. So as</p>	<p>1 Q. And that has a flag as well,</p> <p>2 right?</p> <p>3 A. It does.</p> <p>4 Q. And it says, "less than</p> <p>5 50 percent efficacy, hit call potentially</p> <p>6 confounding by overfitting," right?</p> <p>7 A. Yes.</p> <p>8 Q. Has SOX1 activity been</p> <p>9 associated with ASD or ADHD specifically?</p> <p>10 A. I don't know offhand if SOX1.</p> <p>11 I'm aware that SOX2 has been implicated in</p> <p>12 neurodevelopmental disorders such as ASD. I</p> <p>13 don't recall offhand if SOX1 is.</p> <p>14 But the SOX family of</p> <p>15 transcription factors is highly implicated in</p> <p>16 such neurodevelopmental outcomes.</p> <p>17 Q. In any event, the less than</p> <p>18 50 percent efficacy in hit call potentially</p> <p>19 confounding by overfitting is not -- a</p> <p>20 warning flag is not referenced in your</p> <p>21 report, correct?</p> <p>22 A. It is not.</p> <p>23 Q. On page -- pages -- you discuss</p> <p>24 in your report, it looks like Section 11,</p> <p>25 Roman numeral XI, APAP's mechanisms of</p>
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<p>1 someone who is a neurotoxicologist, it's a</p> <p>2 beautiful curve. It's actually wonderful</p> <p>3 data.</p> <p>4 Q. But it's flagged as noisy data,</p> <p>5 correct?</p> <p>6 A. It's flagged. And so</p> <p>7 computational toxicologists want to have</p> <p>8 systems of checks and balances to make sure</p> <p>9 that the -- that the -- they have ways to</p> <p>10 have alerts. But just because flags are</p> <p>11 stimulated doesn't mean that the data are</p> <p>12 bad.</p> <p>13 So they may very well look at</p> <p>14 this and say, oh, no, actually this looks</p> <p>15 great, and the AC50s that are generated from</p> <p>16 it are good.</p> <p>17 Q. And the last one -- I think</p> <p>18 this is over on your table, page 125 -- is</p> <p>19 the SOX1 assay that you described; is that</p> <p>20 right?</p> <p>21 A. Yes.</p> <p>22 Q. And that one is in -- this</p> <p>23 exhibit is the 6:10 p.m. in the bottom right</p> <p>24 corner graph, right?</p> <p>25 A. I see it, yes.</p>	<p>1 neurodevelopmental injury.</p> <p>2 Do you recall that?</p> <p>3 A. Can you tell me what page that</p> <p>4 is?</p> <p>5 Q. Page 50.</p> <p>6 A. Yes.</p> <p>7 Q. Have you -- I think earlier you</p> <p>8 said you were -- you reviewed and relied upon</p> <p>9 Dr. Cabrera's report, right?</p> <p>10 A. I read his report, and I</p> <p>11 reference it in my report.</p> <p>12 Q. Have you reviewed Dr. Cabrera's</p> <p>13 deposition transcript?</p> <p>14 A. I read his deposition</p> <p>15 transcript.</p> <p>16 Q. And I'll represent to you --</p> <p>17 I'll represent to you that Dr. Cabrera</p> <p>18 testified in his deposition that the core</p> <p>19 pathways for his opinions were oxidative</p> <p>20 stress and endocannabinoid pathways, and that</p> <p>21 for the other proposed mechanisms, at least</p> <p>22 when applying the adverse outcomes pathways,</p> <p>23 that, quote, "there would be gaps in the data</p> <p>24 that would leave a gap in the biologic</p> <p>25 plausibility that would need additional data</p>

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<p>1 to fill in those gaps."</p> <p>2 Do you recall that?</p> <p>3 MS. HUNT: Object to the form</p> <p>4 of the question.</p> <p>5 You can answer, if you recall.</p> <p>6 THE WITNESS: I don't recall</p> <p>7 that.</p> <p>8 (Pearson Exhibit 77 marked for</p> <p>9 identification.)</p> <p>10 QUESTIONS BY MR. PADGETT:</p> <p>11 Q. Okay. And I'll hand you what's</p> <p>12 pages 325 to 326 of Dr. Cabrera's deposition,</p> <p>13 if you want to take a look.</p> <p>14 Can I have it back? I'll go</p> <p>15 ahead and mark it.</p> <p>16 I'm going to hand you what's</p> <p>17 been marked as Exhibit 77. That's pages 325</p> <p>18 to 326 of Dr. Cabrera's report {sic}.</p> <p>19 Do you recall reading this</p> <p>20 testimony at the end of page 325 over to</p> <p>21 page 326 from Dr. Cabrera?</p> <p>22 A. I'll need just a second to look</p> <p>23 at it.</p> <p>24 Q. Sure.</p> <p>25 A. It looks a little bit familiar,</p>	<p>1 A. I would not endorse that</p> <p>2 precisely. I do not -- I don't think that's</p> <p>3 an accurate summarization, no.</p> <p>4 Q. And you don't think that's an</p> <p>5 accurate summarization by Dr. Cabrera, is</p> <p>6 what you're saying?</p> <p>7 A. Correct.</p> <p>8 Q. Okay.</p> <p>9 A. I think there's enough -- there</p> <p>10 is sufficient information about mechanism,</p> <p>11 biological-initiating mechanisms, of damage</p> <p>12 by acetaminophen in nervous system tissues</p> <p>13 beyond oxidative stress and how that leads to</p> <p>14 neurodevelopmental injury in the developing</p> <p>15 brain, and that includes synaptic</p> <p>16 dysfunction, cellular disruption and</p> <p>17 neurodevelopmental cascades that include --</p> <p>18 Q. Sorry.</p> <p>19 A. Sorry.</p> <p>20 -- that include endocrine</p> <p>21 disruption. It includes serotonergic</p> <p>22 alterations, dopaminergic dysfunction, and</p> <p>23 includes various different pathways,</p> <p>24 epigenetic disruption.</p> <p>25 Q. You discuss in your report a</p>
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<p>1 yeah.</p> <p>2 Q. Okay. But he states with</p> <p>3 regard to mechanisms -- or pathways,</p> <p>4 biological systems -- he calls them the core</p> <p>5 pathways -- beyond oxidative stress and</p> <p>6 endocannabinoid pathways that there would --</p> <p>7 quote, "there would be gaps in the data that</p> <p>8 would leave a gap in the biological</p> <p>9 plausibility that would need additional data</p> <p>10 to fill in those gaps," period, end quote.</p> <p>11 Did I read that correctly?</p> <p>12 MS. HUNT: Object to form.</p> <p>13 You can answer.</p> <p>14 THE WITNESS: I'm not sure you</p> <p>15 read that exactly correctly, but I</p> <p>16 think you summarized it sufficiently</p> <p>17 what was stated there.</p> <p>18 QUESTIONS BY MR. PADGETT:</p> <p>19 Q. Do you agree with Dr. Cabrera's</p> <p>20 statement here that beyond the</p> <p>21 endocannabinoid pathways and oxidative stress</p> <p>22 pathway, that the other mechanisms that have</p> <p>23 been -- have gaps in biological plausibility</p> <p>24 that would need additional data to fill in</p> <p>25 those gaps?</p>	<p>1 mechanism related to AM404, correct?</p> <p>2 A. I discuss mechanisms related to</p> <p>3 4-Aminophenol that involve that pathway.</p> <p>4 Q. Okay. When you say 4-Amin --</p> <p>5 say it again?</p> <p>6 A. I think it's 4-Aminophenol.</p> <p>7 Yeah.</p> <p>8 Q. Is that FAAH?</p> <p>9 A. FAAH is the enzyme that's</p> <p>10 involved in the synthesis of that particular</p> <p>11 metabolite.</p> <p>12 Q. Okay. I think you indicate in</p> <p>13 your report a key metabolite of acetaminophen</p> <p>14 is PAP, or p-Aminophenon {sic}?</p> <p>15 A. Sorry. p-Aminophenol, yeah.</p> <p>16 Q. PAP, correct?</p> <p>17 A. Yes.</p> <p>18 Q. Okay.</p> <p>19 A. Yeah.</p> <p>20 Q. And that in the brain and in</p> <p>21 the presence of FAAH, PAP can conjugate with</p> <p>22 arachidonic acid to form AM404; is that</p> <p>23 correct? Is that a correct representation of</p> <p>24 your --</p> <p>25 A. That's my recollection without</p>

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<p style="text-align: right;">Page 222</p> <p>1 seeing it in front of --</p> <p>2 Q. Okay.</p> <p>3 A. -- in front of my -- in front</p> <p>4 of me.</p> <p>5 Q. What percentage of</p> <p>6 acetaminophen is metabolized to PAP?</p> <p>7 MS. HUNT: Object to the form</p> <p>8 of the question.</p> <p>9 You can answer.</p> <p>10 THE WITNESS: I do not know the</p> <p>11 specific number. My recollection is</p> <p>12 it's a small percentage.</p> <p>13 QUESTIONS BY MR. PADGETT:</p> <p>14 Q. Is it more or less than the</p> <p>15 percentage of NAPQI that is formed during</p> <p>16 acetaminophen metabolism?</p> <p>17 And if you want to look to</p> <p>18 page 8 of your report, there's a discussion</p> <p>19 of this.</p> <p>20 A. So on the bottom of page 8, it</p> <p>21 shows a diagram that gives approximate</p> <p>22 metabolic fates of acetaminophen products.</p> <p>23 And to answer your question</p> <p>24 specifically, it says 5 to 10 percent of</p> <p>25 acetaminophen ends up as NAPQI.</p>	<p style="text-align: right;">Page 224</p> <p>1 again, it's a snapshot to give approximate --</p> <p>2 approximations, but they can be helpful as</p> <p>3 a -- as an approximation.</p> <p>4 Q. Okay. But that's what -- those</p> <p>5 numbers are what's reflected in Figure 2 of</p> <p>6 your -- page 8 of your report, right?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And the metabolite --</p> <p>9 metabolism pathway for -- to NAPQI is APAP</p> <p>10 conjugate -- is conju -- is bound with CYP2E1</p> <p>11 to create NAP -- NAPQI, right?</p> <p>12 A. CYP2E1 oxidizes acetaminophen</p> <p>13 to NAPQI, yes.</p> <p>14 Q. Okay. And then GSH,</p> <p>15 essentially an antioxidant that converts</p> <p>16 NAPQI to a harmless metabolite that's</p> <p>17 excreted in the urine, right?</p> <p>18 A. That's an okay-enough</p> <p>19 summarization, yes.</p> <p>20 Q. Okay. And some acetaminophen</p> <p>21 is excreted as is -- in urine in unconjugated</p> <p>22 form, right?</p> <p>23 A. Very little.</p> <p>24 Q. Okay. Is it about 5 percent?</p> <p>25 A. I don't know the exact number,</p>
<p style="text-align: right;">Page 223</p> <p>1 But that's state-dependent.</p> <p>2 That depends on, you know, how much CYP2E1</p> <p>3 there is. CYP2E1 is variable.</p> <p>4 It also depends on how much</p> <p>5 glucuronidation or sulfation is happening to</p> <p>6 the parent molecule.</p> <p>7 It also depends on how much</p> <p>8 parent molecule there is.</p> <p>9 Q. Okay.</p> <p>10 A. It also depends on how much</p> <p>11 glutathione there is, of course.</p> <p>12 Q. And you're referring on page 8</p> <p>13 to Figure 2, right?</p> <p>14 A. To Figure 2, yes.</p> <p>15 Q. Okay. And based on Figure 2,</p> <p>16 you would agree that 60 percent of</p> <p>17 acetaminophen is metabolized through</p> <p>18 glucocorn -- corn -- glucuren -- how do you</p> <p>19 say it?</p> <p>20 A. Glucuronidation.</p> <p>21 Q. Glucuronidation, and 30 percent</p> <p>22 through sulfation, right?</p> <p>23 A. These are approximate numbers.</p> <p>24 There are species differences. There's</p> <p>25 developmental differences. These are --</p>	<p style="text-align: right;">Page 225</p> <p>1 but most of it is processed.</p> <p>2 Q. PAP is not on this graphic in</p> <p>3 Figure 2, correct?</p> <p>4 A. It is not.</p> <p>5 Q. And I don't believe I saw this</p> <p>6 in any study cited in your report, but</p> <p>7 correct me if I'm wrong, but are there any</p> <p>8 studies that have measured AM404 in the human</p> <p>9 embryonic fetal brain?</p> <p>10 MS. HUNT: Object to form.</p> <p>11 You can answer.</p> <p>12 THE WITNESS: I do not know.</p> <p>13 QUESTIONS BY MR. PADGETT:</p> <p>14 Q. Okay. In your opinion, is one</p> <p>15 molecule of AM404 in the fetal brain</p> <p>16 sufficient to cause ASD?</p> <p>17 MS. HUNT: Object to the form</p> <p>18 of the question.</p> <p>19 You can answer.</p> <p>20 THE WITNESS: I do not have any</p> <p>21 knowledge of how much AM404 would be</p> <p>22 required to cause ASD.</p> <p>23 QUESTIONS BY MR. PADGETT:</p> <p>24 Q. And same question for ADHD. Is</p> <p>25 one molecule of AM404 in the fetal brain</p>

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<p>1 sufficient to cause ADHD?</p> <p>2 MS. HUNT: Same objection.</p> <p>3 THE WITNESS: Asking a question</p> <p>4 about an individual molecule causing a</p> <p>5 complex human disease is, I think,</p> <p>6 indicative of how -- why something</p> <p>7 like a weight of evidence is</p> <p>8 necessary, because that's just not how</p> <p>9 disease risk works. We're dealing --</p> <p>10 again, we're dealing with, like,</p> <p>11 complex, pleiotropic disease.</p> <p>12 It's -- so to more directly</p> <p>13 answer your question, I cannot answer</p> <p>14 that question. It's not possible to</p> <p>15 answer that question.</p> <p>16 QUESTIONS BY MR. PADGETT:</p> <p>17 Q. Okay. And to your point about</p> <p>18 a weight of evidence, are you aware of any</p> <p>19 studies that have measured AM404 in human</p> <p>20 adults?</p> <p>21 MS. HUNT: Object to the form</p> <p>22 of the question.</p> <p>23 You can answer.</p> <p>24 THE WITNESS: I have not</p> <p>25 reviewed the literature about whether</p>	<p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. And you said it would lead to a</p> <p>3 human disorder. So the same response would</p> <p>4 be true with regard to ADHD, correct?</p> <p>5 A. Same answer.</p> <p>6 Q. You assert on page 63 of your</p> <p>7 report that it is well-accepted that</p> <p>8 endocannabinoid disruption during pregnancy</p> <p>9 should be avoided, and there you cite ACOG,</p> <p>10 right?</p> <p>11 A. Yes.</p> <p>12 Q. So there you do, in fact,</p> <p>13 believe that ACOG is a valid source of</p> <p>14 medical opinion, correct?</p> <p>15 MS. HUNT: Object to the form</p> <p>16 of the question.</p> <p>17 You may answer.</p> <p>18 THE WITNESS: Citing a</p> <p>19 particular reference means that that</p> <p>20 particular reference is what I'm</p> <p>21 referring to to support that</p> <p>22 statement.</p> <p>23 (Pearson Exhibit 75 marked for</p> <p>24 identification.)</p> <p>25</p>
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<p>1 AM404 has been measured in human</p> <p>2 biospecimens. So I don't know.</p> <p>3 QUESTIONS BY MR. PADGETT:</p> <p>4 Q. And is it your opinion that</p> <p>5 AM404 increases anandamide and that this</p> <p>6 increase of anandamide disrupts the</p> <p>7 endocannabinoid system?</p> <p>8 A. My understanding is that AM404</p> <p>9 is involved in endocannabinoid signaling, and</p> <p>10 disruption to the endocannabinoid signaling</p> <p>11 system is -- can perturb neurodevelopment.</p> <p>12 Q. And do you have any</p> <p>13 understanding of the level at which a</p> <p>14 decrease of AM404 would sufficiently perturb</p> <p>15 the endocannabinoid system to result in an</p> <p>16 increased risk of ASD?</p> <p>17 MS. HUNT: Object to form.</p> <p>18 You can answer.</p> <p>19 THE WITNESS: That is not my</p> <p>20 expertise. I'm not a person who is</p> <p>21 trained in the dosimetry of AM404 in</p> <p>22 the human brain to determine what the</p> <p>23 levels are that are required to lead</p> <p>24 to a human disorder. That's outside</p> <p>25 of my training.</p>	<p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. I'm going to hand you what's</p> <p>3 been marked as Exhibit Number 75. Is that</p> <p>4 the source that you're referring to with</p> <p>5 regard to your citation to ACOG?</p> <p>6 A. I believe it is. Yes.</p> <p>7 Q. And that is a flyer from ACOG</p> <p>8 warning about using marijuana while pregnant,</p> <p>9 correct?</p> <p>10 MS. HUNT: Object to the form</p> <p>11 of the question.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: I'm sorry. The</p> <p>14 question is whether this is a flyer?</p> <p>15 QUESTIONS BY MR. PADGETT:</p> <p>16 Q. Is that a -- is that -- will</p> <p>17 you confirm that Exhibit 78 is an ACOG flyer</p> <p>18 advising against the use of marijuana during</p> <p>19 pregnancy? Correct?</p> <p>20 A. This is a -- this is a couple</p> <p>21 of documents from ACOG that discuss the topic</p> <p>22 of marijuana in pregnancy.</p> <p>23 Q. And the bulletin that's</p> <p>24 Exhibit 78, the ACOG bulletin, states, quote,</p> <p>25 "Research is limited on the forms of</p>

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<p style="text-align: right;">Page 230</p> <p>1 marijuana use during pregnancy because all of</p> <p>2 the possible harms are not fully known. ACOG</p> <p>3 recommends that anyone who is pregnant,</p> <p>4 planning to get pregnant or breastfeeding not</p> <p>5 use marijuana," period, end quote.</p> <p>6 Did I read that correctly?</p> <p>7 A. You did.</p> <p>8 Q. And THC use during pregnancy is</p> <p>9 discouraged because research is limited on</p> <p>10 the harms of marijuana use during pregnancy,</p> <p>11 and all of the possible harms are not fully</p> <p>12 known, correct?</p> <p>13 MS. HUNT: Object to form.</p> <p>14 You can answer.</p> <p>15 THE WITNESS: You were asking</p> <p>16 me about THC use? I didn't understand</p> <p>17 the question.</p> <p>18 MR. PADGETT: Can you read it</p> <p>19 back, please?</p> <p>20 Strike that.</p> <p>21 QUESTIONS BY MR. PADGETT:</p> <p>22 Q. According to this ACOG</p> <p>23 bulletin, THC use during pregnancy is</p> <p>24 discouraged because research is limited on</p> <p>25 the harms of marijuana use during pregnancy</p>	<p style="text-align: right;">Page 232</p> <p>1 Q. Do you believe it's appropriate</p> <p>2 to extrapolate from the effects of one</p> <p>3 endocannabinoid compound to make a causation</p> <p>4 argument about another compound acting on an</p> <p>5 endocannabinoid system?</p> <p>6 A. I think -- I think it's -- I</p> <p>7 think that knowing that a particular ligand</p> <p>8 of receptors affecting neurodevelopment can</p> <p>9 tell you that. You have to be careful with</p> <p>10 other known ligands to those receptors when a</p> <p>11 full safety profile of that particular</p> <p>12 chemical in question has not been performed.</p> <p>13 Q. And we're talking about ASD or</p> <p>14 ADHD. Wouldn't you need to be specific as to</p> <p>15 the particular neurochemicals or transmitters</p> <p>16 that have been linked with ASD in terms of</p> <p>17 perturbing of the endocannabinoid system?</p> <p>18 MS. HUNT: Object to form.</p> <p>19 You can answer.</p> <p>20 THE WITNESS: So with ASD and</p> <p>21 ADHD -- so we're talking about now two</p> <p>22 different disorders, endocannabinoids</p> <p>23 and now neurotransmitters. So now I'm</p> <p>24 a little bit confused about what</p> <p>25 specifically you're asking me.</p>
<p style="text-align: right;">Page 231</p> <p>1 and all of the possible harms are not fully</p> <p>2 known, right?</p> <p>3 MS. HUNT: Object to form.</p> <p>4 You can answer.</p> <p>5 THE WITNESS: I want to make</p> <p>6 sure I understand the question.</p> <p>7 So you're asking whether ACOG</p> <p>8 is recommending that pregnant people</p> <p>9 don't use THC while pregnant because</p> <p>10 all of the harms aren't known? And</p> <p>11 you're asking me to say yes or no to</p> <p>12 that?</p> <p>13 QUESTIONS BY MR. PADGETT:</p> <p>14 Q. Is that your understanding?</p> <p>15 That's my question.</p> <p>16 A. I don't -- I wouldn't fully</p> <p>17 agree with that, because as they're saying</p> <p>18 here, they're saying possible effects on your</p> <p>19 fetus - disruption of brain development</p> <p>20 before birth, smaller size at birth. They're</p> <p>21 listing many, many effects.</p> <p>22 So it's not just because the</p> <p>23 possible effects aren't known. I can't</p> <p>24 endorse that particular response to the</p> <p>25 affirmative as you phrased the question.</p>	<p style="text-align: right;">Page 233</p> <p>1 So specificity about which</p> <p>2 chemicals that act as ligands for the</p> <p>3 endocannabinoid system?</p> <p>4 QUESTIONS BY MR. PADGETT:</p> <p>5 Q. Yes.</p> <p>6 A. Or neurotransmitters?</p> <p>7 So you're not asking me about</p> <p>8 neurotransmitters?</p> <p>9 Q. Not right now.</p> <p>10 A. Okay. So, no.</p> <p>11 Q. Same question about</p> <p>12 neurotransmitters.</p> <p>13 Don't you need to know the</p> <p>14 particular neurotransmitters that have been</p> <p>15 linked with ASD in terms of perturbing of the</p> <p>16 endocannabinoid system in making a causal</p> <p>17 assessment?</p> <p>18 A. I'm not certain I understand</p> <p>19 what you mean with respect to</p> <p>20 endocannabinoids and now neurotransmitters.</p> <p>21 Q. What specific neurochemicals</p> <p>22 have been identified as perturbing the</p> <p>23 endocannabinoid system as cause -- as</p> <p>24 specifically causing ASD?</p> <p>25 MS. HUNT: Object to form.</p>

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<p style="text-align: right;">Page 234</p> <p>1 You can answer. 2 THE WITNESS: I'm really having 3 a hard time understanding what you're 4 asking me. 5 So specificity about 6 neurotransmitters that are involved in 7 ASD and ADHD and how that relates to 8 endocannabinoids? 9 Look, I think what we're 10 discussing here is the involvement of 11 the endocannabinoid system and whether 12 acetaminophen is perturbing 13 endocannabinoid system. 14 If we're talking about the 15 endocannabinoid system as a mechanism 16 by which acetaminophen is disturbing 17 neurodevelopment, what that has to do 18 with neurotransmitters, serotonin, 19 dopamine, you know, norepinephrine, et 20 cetera, I don't see the link here, 21 like what -- how I'm supposed to 22 answer your question. 23 QUESTIONS BY MR. PADGETT: 24 Q. Let me ask you this way. 25 Do you -- can you identify a</p>	<p style="text-align: right;">Page 236</p> <p>1 you all the way back to page 10 of your 2 amended expert report. 3 You have a statement there that 4 says that a fetus has, quote, "Less ability 5 to detoxify NAPQI," period, end quote. 6 It's at the very -- towards the 7 very bottom of the page. 8 Do you see that? 9 A. Yes. 10 Q. Okay. Aside from the statement 11 about lower glucuronidation capacity, do you 12 have any other studies supporting the 13 proposition that fetuses have less ability to 14 detoxify NAPQI? 15 A. It's well-understood that the 16 hepatic -- the liver enzymes and liver 17 activity of embryos and fetuses are limited, 18 so it's not until late term and postnatal 19 that the activity of the liver is fully on 20 board. So the fetus is relying on maternal 21 detoxification to some degree. 22 Q. Okay. 23 A. And I don't know exactly where 24 I have that cited in here, but that's a 25 well-understood metabolic and toxicological</p>
<p style="text-align: right;">Page 235</p> <p>1 single study that suggests or reports that 2 AM404 has neurodevelopmental effects, 3 including the development of ASD or ADHD? 4 MS. HUNT: Object to the form 5 of the question. 6 You can answer. 7 THE WITNESS: If AM404 has 8 neurodevelopmental effects. 9 I do not recall studies that 10 specifically look at AM404 and 11 directly linking to neurodevelopmental 12 effects in humans. 13 MR. PADGETT: We've been going 14 over an hour. Do you want to take a 15 break? 16 MS. HUNT: Sounds good to me. 17 VIDEOGRAPHER: The time right 18 now is 2:41 p.m., and we're off the 19 record. 20 (Off the record at 2:41 p.m.) 21 VIDEOGRAPHER: The time right 22 now is 3:02 p.m., and we're back on 23 the record. 24 QUESTIONS BY MR. PADGETT: 25 Q. Dr. Pearson, I'm going to take</p>	<p style="text-align: right;">Page 237</p> <p>1 phenomenon. 2 Q. What about levels of GSH in the 3 fetal brain, do you have any understanding of 4 the levels of the GSH that are present in the 5 fetal brain shown by any scientific research? 6 MS. HUNT: Object to form. 7 You can answer. 8 THE WITNESS: There's the study 9 that we discussed earlier that had 10 some limitations in terms of controls 11 but nevertheless gave some information 12 on this. And that is Beck, in rat, 13 shows us that low weight files are 14 reduced, that glutathione was reduced 15 in the fetal brain relative to other 16 tissues, and that acetaminophen 17 changes that. 18 And so there's developmental 19 dynamics of glutathione levels in 20 fetal tissues and in fetal brain, and 21 those change over time. 22 QUESTIONS BY MR. PADGETT: 23 Q. But you're talking about rat -- 24 A. I am talking about rat. 25 Q. Okay. What about studies about</p>

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<p style="text-align: right;">Page 238</p> <p>1 GSH in the fetal human brain?</p> <p>2 MS. HUNT: Object to the form</p> <p>3 of the question.</p> <p>4 You can answer.</p> <p>5 QUESTIONS BY MR. PADGETT:</p> <p>6 Q. Any do you have -- are you</p> <p>7 aware of any studies looking at that?</p> <p>8 A. Off the top of my head, I'm not</p> <p>9 sure if the glutathione in human embryos or</p> <p>10 fetuses has been measured. It may very well</p> <p>11 have.</p> <p>12 Q. I'm going to hand you what has</p> <p>13 been previously marked as Exhibit 43. It was</p> <p>14 in -- from Dr. Louie's deposition. It's got</p> <p>15 a chicken scratch from Dr. Louie on it.</p> <p>16 Have you -- have you read this</p> <p>17 article before?</p> <p>18 A. Let me look at the figures and</p> <p>19 see if I recognize it.</p> <p>20 I don't know if I relied on</p> <p>21 this or looked at it or not. I don't</p> <p>22 recognize it. But I may have.</p> <p>23 Q. I do not believe it was on your</p> <p>24 list of materials, but you also don't recall</p> <p>25 looking at it within the past month or two?</p>	<p style="text-align: right;">Page 240</p> <p>1 strike that.</p> <p>2 I'm going to hand you what's</p> <p>3 been marked previously in Dr. Louie's</p> <p>4 deposition as Exhibit 40, ask do you</p> <p>5 recognize that study?</p> <p>6 A. I do not recognize this study</p> <p>7 just based on the title page.</p> <p>8 Q. If you turn to Table 2 in</p> <p>9 Figure B of this -- and this is the Dutheil</p> <p>10 2009 study, correct?</p> <p>11 A. Yes.</p> <p>12 Q. And this is looking at CYP2E1</p> <p>13 mRNA expression in the human brain and in the</p> <p>14 liver and various other -- specifically in</p> <p>15 the liver and various parts of the human</p> <p>16 brain, correct?</p> <p>17 MS. HUNT: I would just --</p> <p>18 sorry. I object to the form.</p> <p>19 You can answer, if you have a</p> <p>20 chance.</p> <p>21 THE WITNESS: Which figure are</p> <p>22 you wanting to --</p> <p>23 QUESTIONS BY MR. PADGETT:</p> <p>24 Q. Table 2.</p> <p>25 A. Table 2. Okay. I'm looking at</p>
<p style="text-align: right;">Page 239</p> <p>1 A. I do not recall looking at it,</p> <p>2 no.</p> <p>3 Q. Okay. And this article reports</p> <p>4 on table -- in specifically Table 2, GSH</p> <p>5 levels in the fetal brain and liver of -- as</p> <p>6 of 13 weeks, correct?</p> <p>7 A. I see that in Table 2.</p> <p>8 Q. Okay. And you indicated</p> <p>9 earlier that acetaminophen -- you said that</p> <p>10 the -- that the P -- we rely on the mother's</p> <p>11 metabolism in the liver to deal with NAPQI;</p> <p>12 is that right?</p> <p>13 A. I did not say that.</p> <p>14 Q. Okay. What did you mean? You</p> <p>15 were talking about it earlier.</p> <p>16 A. I was saying that the liver on</p> <p>17 the whole is not fully functional in a</p> <p>18 developing embryo or fetus, and that some of</p> <p>19 the detoxification of circulating xenobiotics</p> <p>20 would require hepatic function of the mother.</p> <p>21 Q. Okay. At least here, brain GSH</p> <p>22 shows 80 nanomole per milligrams systolic</p> <p>23 protein for GSH, correct?</p> <p>24 A. Nanograms per milligram, yes.</p> <p>25 Q. Okay. And have you reviewed --</p>	<p style="text-align: right;">Page 241</p> <p>1 Table 2.</p> <p>2 Q. Do you see that with regard to</p> <p>3 the liver, the expression of CYP2E1 mRNA</p> <p>4 compared to the brain is 1,300-plus times</p> <p>5 larger --</p> <p>6 MS. HUNT: Object to the form.</p> <p>7 QUESTIONS BY MR. PADGETT:</p> <p>8 Q. -- in the liver than in the</p> <p>9 brain?</p> <p>10 MS. HUNT: Sorry.</p> <p>11 Object to the form of the</p> <p>12 question.</p> <p>13 You may answer.</p> <p>14 QUESTIONS BY MR. PADGETT:</p> <p>15 Q. More than a thousand times</p> <p>16 higher, correct?</p> <p>17 MS. HUNT: Same objection.</p> <p>18 THE WITNESS: So I've not</p> <p>19 looked at the study before, but if</p> <p>20 you're asking me the question whether</p> <p>21 the number 550,000 is larger than 413,</p> <p>22 a thousand times larger, the answer to</p> <p>23 that would be yes.</p> <p>24 QUESTIONS BY MR. PADGETT:</p> <p>25 Q. Have you reviewed Dr. McGill's</p>

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<p>1 report in this case?</p> <p>2 A. I did not read his full report,</p> <p>3 but I looked over parts of it.</p> <p>4 Q. Did you review the parts of it</p> <p>5 related to the levels of CYP2E1 as compared</p> <p>6 to GSH in the human and rodent brains</p> <p>7 compared to the liver?</p> <p>8 MS. HUNT: Object to the form</p> <p>9 of the question.</p> <p>10 Answer, if you can.</p> <p>11 THE WITNESS: I did not review</p> <p>12 all of that. Part of what I read I</p> <p>13 did not feel was accurate, so I didn't</p> <p>14 spend the precious time that I had</p> <p>15 looking at the rest of it.</p> <p>16 QUESTIONS BY MR. PADGETT:</p> <p>17 Q. Which part did you feel was not</p> <p>18 accurate?</p> <p>19 A. So various parts of it I did</p> <p>20 not feel were accurate. I can't quote to you</p> <p>21 which parts of it.</p> <p>22 But just to give you an</p> <p>23 example, I can already tell you issues with</p> <p>24 the interpretation of this. This is giving</p> <p>25 you transcript levels, which is not</p>	<p>1 levels of CYP2E1 are in the fetal brain?</p> <p>2 MS. HUNT: Object to the form</p> <p>3 of the question.</p> <p>4 You can answer.</p> <p>5 THE WITNESS: Under what</p> <p>6 circumstances? Under any circumstance</p> <p>7 or under the circumstances of</p> <p>8 acetaminophen exposure?</p> <p>9 QUESTIONS BY MR. PADGETT:</p> <p>10 Q. Under the circumstances of</p> <p>11 acetaminophen exposure.</p> <p>12 A. Baker, et al., 2023.</p> <p>13 Q. Can you say that again?</p> <p>14 A. In our own study, Baker, et</p> <p>15 al., 2023, demonstrates that.</p> <p>16 Q. And what does that demonstrate?</p> <p>17 A. It demonstrates that there's</p> <p>18 oxidative stress in the brain. If there's</p> <p>19 oxidative stress in the brain, it</p> <p>20 demonstrates that the antioxidant systems</p> <p>21 such as glutathione are insufficient to deal</p> <p>22 with the prooxidant imbalance. As do any of</p> <p>23 the other studies that show that there's</p> <p>24 elevations in prooxidants or oxidative</p> <p>25 stress.</p>
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<p>1 sufficient here.</p> <p>2 I don't know whether they have</p> <p>3 controlled for, for instance, the million map</p> <p>4 reads. I don't know if they're controlling</p> <p>5 for the size of the -- I don't know if</p> <p>6 they're controlling here for the protein</p> <p>7 levels.</p> <p>8 This is just transcripts.</p> <p>9 There's a number of issues here of just</p> <p>10 relying on only transcript level. So making</p> <p>11 these tissue-level comparisons is</p> <p>12 insufficient with -- in terms of</p> <p>13 understanding the abundance of the enzyme.</p> <p>14 It would be better to support</p> <p>15 this with -- or it would be helpful to</p> <p>16 support this with either immunolabeling,</p> <p>17 Western Blot, something of the sort,</p> <p>18 proteomics, if one was to try to make the</p> <p>19 conclusion that -- you know, the relative</p> <p>20 abundance of the enzyme. This is just</p> <p>21 message.</p> <p>22 Q. Are you aware of any studies</p> <p>23 that show that in the fetal brain the levels</p> <p>24 of GSH are not abundant enough to take care</p> <p>25 of NAPQI that would be created by whatever</p>	<p>1 In other words, you don't have</p> <p>2 to be able to measure glutathione. You don't</p> <p>3 necessarily have to measure CYP2E1. You</p> <p>4 don't necessarily have to measure or prove</p> <p>5 that the glutathione is insufficient when you</p> <p>6 can show that there's oxidative damage.</p> <p>7 When there's evidence of</p> <p>8 oxidative damage, you don't have to measure</p> <p>9 the CYP2E1. You don't have to measure the</p> <p>10 glutathione. Or you don't have to measure</p> <p>11 the radical itself, which is a very difficult</p> <p>12 thing to do.</p> <p>13 There's plenty of studies that</p> <p>14 show the damage of the radical and the</p> <p>15 insufficiency of the antioxidant in the face</p> <p>16 of the acetaminophen exposure.</p> <p>17 Q. Are you aware of any -- strike</p> <p>18 that.</p> <p>19 Have you -- are you familiar</p> <p>20 with the Human Protein Atlas?</p> <p>21 A. I'm aware of the Human Protein</p> <p>22 Atlas, yes.</p> <p>23 Q. Have you reviewed levels of</p> <p>24 CYP2E1 protein expression and mRNA expression</p> <p>25 for CYP2E1 in the Human Atlas?</p>

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<p style="text-align: right;">Page 246</p> <p>1 A. Yes. In my expert report, I 2 provide data -- I believe it's from the Human 3 Protein Atlas -- showing brain levels of 4 CYP2E1 to give an example of how in various 5 brain regions the expression can vary but 6 that it is expressed. 7 Oh, that's the BrainSpan. 8 Excuse me. It's not the Human Protein Atlas, 9 but it's BrainSpan. Just a similar type of a 10 database, though. 11 Q. Okay. 12 A. I'll point something out -- 13 else that I believe is relevant to that as 14 well. 15 If you compare something like 16 the liver to the brain, the relative 17 abundance of something like CYP2E1 shouldn't 18 be compared on the same scale because, for 19 instance, in the liver, if you have lower 20 levels of an antioxidant in one versus the 21 other, or lower levels of an enzyme that 22 converts a drug, a parent drug, to a 23 prooxidant, even low levels of that enzyme 24 can be more harmful in an organ that doesn't 25 regenerate, like the brain, versus a tissue,</p>	<p style="text-align: right;">Page 248</p> <p>1 So saying that there's -- oh, 2 there's smaller amounts of CYP2E1 versus the 3 liver, it's not a fair comparison. 4 Q. Can you identify a study that 5 quantifies the level of imbalance needed 6 between GSH and oxidative stress in the fetal 7 brain to cause ASD or ADHD? 8 MS. HUNT: Object to form. 9 You can answer. 10 THE WITNESS: That sort of a 11 study is not necessary when you can 12 just introduce the perturbation, agent, 13 drug in question and then look if you 14 have relevant outcomes. 15 It's not necessary to sort of 16 do this sort of mathematical 17 hypothetical and say, what's the 18 relative amount, when you can actually 19 just do the experiment. Does the test 20 agent elicit the effect. 21 QUESTIONS BY MR. PADGETT: 22 Q. My question -- my question is, 23 can you identify a study that quantifies the 24 level of imbalance needed between GSH and 25 oxidative stress in the fetal brain to cause</p>
<p style="text-align: right;">Page 247</p> <p>1 like the liver, that can regenerate. 2 You can remove 90 percent of 3 your liver, and it can regenerate. You can 4 damage a very small part of your brain, and 5 it doesn't regenerate. 6 So the relevance of this being 7 is that if you damage neurons in your brain 8 and they die, or they become comprised, they 9 cannot regenerate in the same way that your 10 liver can. 11 So the liver has different 12 mechanisms to deal with damage. So 13 hepatocytes in the liver, if they're damaged, 14 if there's DNA damage, if there's oxidative 15 stress, they prefer to just die and replace 16 themselves. 17 Your brain cannot and does not 18 do that in the same way. 19 So the antioxidant systems are 20 different. The way that they respond to 21 damage is different. 22 So small amounts of damage, 23 small amount of prooxidants in discrete areas 24 in the brain matter, and the impacts of that 25 are much, much larger.</p>	<p style="text-align: right;">Page 249</p> <p>1 ASD or ADHD? 2 MS. HUNT: Same objection. 3 QUESTIONS BY MR. PADGETT: 4 Q. I understand you're saying you 5 don't need that, but I'm asking, do you -- 6 can you identify one that does that? 7 A. Can I identify a study that 8 compares the amount of imbalance between GSH 9 and oxidative stress that leads to ADHD or 10 ASD? 11 Q. Yes. 12 A. That's not how scientists 13 approach these problems. 14 Scientists approach these 15 problems by sort of a scientific method by 16 saying, there's the -- there's a question, 17 does this particular substance cause this 18 effect; what's our hypothesis; what's our 19 prediction; how can we set up the experiment 20 and look at it. 21 I don't think I can answer your 22 question the way that it's phrased. 23 Q. My question is, can you 24 identify a study that compares the amount of 25 imbalance between GSH and oxidative stress</p>

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<p style="text-align: right;">Page 250</p> <p>1 that leads to ADHD or ASD.</p> <p>2 If your position is that my</p> <p>3 question is irrelevant, fine.</p> <p>4 But can you identify such a</p> <p>5 study?</p> <p>6 MS. HUNT: Objection. Asked</p> <p>7 and answered.</p> <p>8 You can answer again.</p> <p>9 THE WITNESS: Well, I'll try to</p> <p>10 make it simpler.</p> <p>11 As my testimony from earlier in</p> <p>12 the day stated, the reason why the</p> <p>13 question would be irrelevant is</p> <p>14 because we're talking about health</p> <p>15 outcomes that are highly</p> <p>16 heterogeneous, that do not involve a</p> <p>17 singular pathology, a singular tumor,</p> <p>18 a singular, you know, break in a bone</p> <p>19 or something like that that you could</p> <p>20 point to to say that, okay, this is</p> <p>21 the thing that leads to the behavioral</p> <p>22 outcome that you could say, oh, that's</p> <p>23 what we can pinpoint, say that is the</p> <p>24 individual thing, and then create that</p> <p>25 calculation.</p>	<p style="text-align: right;">Page 252</p> <p>1 attention in the five-choice serial-reaction</p> <p>2 test in mice.</p> <p>3 Q. But not statistically</p> <p>4 significant?</p> <p>5 A. Not statistically significant.</p> <p>6 Q. Okay.</p> <p>7 A. And multiple different</p> <p>8 endocrine oxidative stress, DNA-damage-</p> <p>9 related changes in the brains of the mice</p> <p>10 that were prenatally exposed.</p> <p>11 Q. Can we agree that studies of</p> <p>12 increased oxidative stress in individuals</p> <p>13 with ASD or ADHD involve measurements taken</p> <p>14 years after those individuals were born?</p> <p>15 Correct?</p> <p>16 A. Some studies that look at</p> <p>17 individuals diagnosed with ASD or ADHD, those</p> <p>18 biomarker studies were collected from</p> <p>19 individuals after diagnosis. Not all of</p> <p>20 them.</p> <p>21 Q. Carey '22 was a study that</p> <p>22 looked at oxidative biomarkers during</p> <p>23 gestation, correct?</p> <p>24 A. I don't have that study in</p> <p>25 front of me, so I can't speak to it.</p>
<p style="text-align: right;">Page 251</p> <p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. Baker 2023, the behavioral</p> <p>3 studies there did not show any changes</p> <p>4 consistent with the ADHD model of attention</p> <p>5 deficits, correct?</p> <p>6 MS. HUNT: Objection.</p> <p>7 Misstates evidence.</p> <p>8 You can answer.</p> <p>9 THE WITNESS: So --</p> <p>10 MR. PADGETT: Object to form</p> <p>11 is -- pursuant to the order.</p> <p>12 MS. HUNT: Yeah, you should</p> <p>13 have tell Ali Brown that for her next</p> <p>14 deposition.</p> <p>15 QUESTIONS BY MR. PADGETT:</p> <p>16 Q. Go ahead.</p> <p>17 A. In the Baker 2023 paper, we</p> <p>18 showed disruptions to motor activation. We</p> <p>19 showed disturbances to pup ultrasonic</p> <p>20 vocalizations, which is a neurodevelopmental</p> <p>21 phenotype that's early in development. And</p> <p>22 we showed suggestive, perhaps behavioral --</p> <p>23 behaviorally relevant but not statistically</p> <p>24 significant changes in impulsive, relevant</p> <p>25 and attentional -- attentioned -- sorry,</p>	<p style="text-align: right;">Page 253</p> <p>1 (Pearson Exhibit 78 marked for</p> <p>2 identification.)</p> <p>3 QUESTIONS BY MR. PADGETT:</p> <p>4 Q. Dr. Pearson, I'm going to hand</p> <p>5 you what's been marked as Exhibit 78.</p> <p>6 Is that -- first of all, are</p> <p>7 you familiar with the Carey '22 -- 2022</p> <p>8 study?</p> <p>9 A. I'm not sure --</p> <p>10 Q. Actually, the Carey -- now the</p> <p>11 Carey -- that was the online version in 2022.</p> <p>12 Actually, are you familiar with</p> <p>13 the published 2023 Carey study?</p> <p>14 A. I don't recall looking at the</p> <p>15 study.</p> <p>16 Q. So you have not reviewed this</p> <p>17 study?</p> <p>18 A. I do not recall having looked</p> <p>19 at this study, no.</p> <p>20 Q. You want to take a moment to</p> <p>21 review it?</p> <p>22 A. Yeah. If I could have just a</p> <p>23 couple of minutes, that would be great.</p> <p>24 Okay. I feel like I have a</p> <p>25 quick -- a quick glance of it, have a feel</p>

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<p>1 for it.</p> <p>2 Q. Can you turn to page 2976?</p> <p>3 A. Okay.</p> <p>4 Q. Left column, about halfway</p> <p>5 down.</p> <p>6 A. Yes.</p> <p>7 Q. You see the word -- the</p> <p>8 sentence that starts "However"?</p> <p>9 A. You said left column halfway</p> <p>10 down or right column?</p> <p>11 Q. Left column, halfway down.</p> <p>12 A. Yes.</p> <p>13 Q. And it says, quote, "However,</p> <p>14 retrospective studies in children already</p> <p>15 diagnosed with ASD cannot provide evidence as</p> <p>16 to whether oxidative stress differences are a</p> <p>17 cause or a consequence of ASD," period, end</p> <p>18 quote.</p> <p>19 Did I read that right?</p> <p>20 A. You did.</p> <p>21 Q. Do you agree with that?</p> <p>22 A. Those studies have limitations</p> <p>23 in that regard, certainly.</p> <p>24 Q. When you say "in that regard,"</p> <p>25 you're -- you mean with regard to determining</p>	<p>1 THE WITNESS: I wouldn't agree</p> <p>2 with that. The abstract says,</p> <p>3 "Results from this cohort with</p> <p>4 increased risk for autism do not</p> <p>5 support a strong relationship between</p> <p>6 oxidative stress in late pregnancy and</p> <p>7 autism-related outcomes."</p> <p>8 They do not say there's no</p> <p>9 relationship.</p> <p>10 QUESTIONS BY MR. PADGETT:</p> <p>11 Q. There was not a statistically</p> <p>12 significant relationship of such an</p> <p>13 association, agreed?</p> <p>14 A. They are underpowered, so they</p> <p>15 are not able to fully state that with</p> <p>16 confidence.</p> <p>17 Q. Where do they state that</p> <p>18 they're underpowered?</p> <p>19 A. I didn't read the whole</p> <p>20 article, but I'm looking at their sample</p> <p>21 size, so...</p> <p>22 They have a sample size of 30</p> <p>23 in the autism group.</p> <p>24 Q. Are you aware of any other</p> <p>25 study looking at gestational exposure and</p>
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<p>1 etiology during conception versus as a</p> <p>2 consequence of ASD?</p> <p>3 A. I would in general agree with</p> <p>4 their statement, is what I'm saying.</p> <p>5 Q. And would you agree that the</p> <p>6 same is true with regard to whether oxidative</p> <p>7 stress differences are a cause or a</p> <p>8 consequence of ADHD? Differences seen in</p> <p>9 ADHD patients?</p> <p>10 A. I think this statement would</p> <p>11 apply to that as well.</p> <p>12 This is why we need preclinical</p> <p>13 studies as well.</p> <p>14 Q. And the Carey 2023 study that</p> <p>15 is Exhibit 78 looked at oxidative stress</p> <p>16 biomarkers during gestation, correct?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And it determined that</p> <p>19 increased oxidative stress during gestation</p> <p>20 did not have -- during late pregnancy did not</p> <p>21 show a relationship with increased risk of</p> <p>22 autism clinical diagnoses, correct?</p> <p>23 MS. HUNT: Object to the form</p> <p>24 of the question.</p> <p>25 You can answer.</p>	<p>1 increased oxidative stress during gestation</p> <p>2 and clinical -- and any association with</p> <p>3 clinical diagnoses of autism spectrum</p> <p>4 disorder?</p> <p>5 MS. HUNT: Object to the form</p> <p>6 of the question.</p> <p>7 You can answer.</p> <p>8 THE WITNESS: So your question</p> <p>9 is, am I aware of any other studies</p> <p>10 that look at oxidative stress</p> <p>11 biomarkers and autism or ADHD</p> <p>12 outcomes?</p> <p>13 QUESTIONS BY MR. PADGETT:</p> <p>14 Q. Autism clinical diagnosis</p> <p>15 outcomes.</p> <p>16 A. Yes. There is a study that</p> <p>17 looked at hydroxyguanosine in cord blood, and</p> <p>18 that is by -- oh, who did that study?</p> <p>19 Q. Are you thinking of the Anand</p> <p>20 study?</p> <p>21 A. Anand. Thank you.</p> <p>22 Q. That was ADHD, though, right?</p> <p>23 A. That was ADHD, yes. That was</p> <p>24 not autism.</p> <p>25 And there's multiple postmortem</p>

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<p>1 brain tissue studies looking at oxidative 2 stress markers and autism. 3 Q. That goes back to the 4 consequence or causation issue that we 5 discussed earlier, right? 6 A. It would. 7 Q. Anand -- are you referring to 8 Anand 2021? 9 (Pearson Exhibit 79 marked for 10 identification.) 11 QUESTIONS BY MR. PADGETT: 12 Q. I'm going to hand you what's 13 been marked as Exhibit 79. 14 Is this the Anand 2021 study 15 that you were referring to? 16 A. It is. 17 Q. And this examined cord blood 18 and a specific -- well, you -- yeah, you 19 discuss this at page 52 of your report. 20 You state that it showed, "high 21 concentrations of acetaminophen have been 22 shown to be associated with higher levels of 23 a specific biomarker of oxidative stress and 24 higher odds of ADHD." 25 Is that -- is that correct?</p>	<p>1 snapshot of fetal metabolism? 2 So cord blood -- I would agree 3 that cord blood provides fetal -- a 4 window into fetal metabolism. 5 If you're asking whether it's 6 only representing a time point of a 7 window of gestation, that would be 8 accurate. 9 QUESTIONS BY MR. PADGETT: 10 Q. Yeah. 11 And that window is right around 12 the time of delivery? 13 A. It represents a window from the 14 time -- from the -- that reflects a limited 15 time from the birth window. 16 Q. And based on the half-life of 17 acetaminophen in the human body, that time 18 window would be no more than a day or two 19 within the date of delivery, correct? 20 A. I think the actual time that it 21 represents could represent longer than what's 22 known as the typical half-life of 23 acetaminophen in non-gestating individual -- 24 like a nonfetal condition, but it's not going 25 to be -- it's not going to be much longer</p>
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<p>1 A. I'm just going to go to that 2 page in my report real quick. 3 Yes. 4 Q. And it states that the children 5 with cord acetaminophen in greater than 50th 6 percentile -- so that's in the top half -- 7 had higher odds of ADHD when the -- when the 8 cord 8-hydroxydeoxyguanosine levels were less 9 than or equal to 50th percentile. 10 Is that right? 11 MS. HUNT: Object to form. 12 You can answer. 13 THE WITNESS: What this study 14 found was that the biomarker was 15 linearly associated with ADHD traits 16 when you looked at the top half of the 17 distribution of the biomarker. 18 QUESTIONS BY MR. PADGETT: 19 Q. Would you agree that cord blood 20 only provides a snapshot of fetal metabolism? 21 MS. HUNT: Object to the form 22 of the question. 23 You can answer. 24 THE WITNESS: Would I agree 25 that cord blood only provides a</p>	<p>1 than that, certainly. 2 Q. Okay. You state at page 53 of 3 your report that "given the early life 4 neuroinflammatory etiology of ASD and ADHD, 5 any stressor that can cause oxidative 6 stress or" -- "and/or inflammatory signaling 7 has a potential to trigger the cellular and 8 synaptic changes that underline" -- "underlie 9 ADHD." 10 Did I read that correctly? 11 A. Let me get to where it says 12 that. 13 Is that towards the top or -- 14 you said that's on 53? 15 Q. Yes. 16 A. I don't see exactly where it 17 says that. Maybe you can help me find that. 18 MS. HUNT: I think your page 19 numbers may be off. 20 MR. PADGETT: Yeah. 21 MS. HUNT: Sorry. 22 MR. PADGETT: Well, I'm looking 23 at your -- yes. 24 QUESTIONS BY MR. PADGETT: 25 Q. Sorry. Page 54.</p>

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<p>1 A. Okay.</p> <p>2 Q. It's the end of -- under</p> <p>3 number 3, Oxidative Stress and Inflammation.</p> <p>4 "Given the early life and</p> <p>5 neuroinflammatory etiology of ASD and ADHD,</p> <p>6 any stressor that can cause oxidative stress</p> <p>7 and/or inflammatory signaling has the</p> <p>8 potential to trigger the cellular and</p> <p>9 synaptic tinges that underlie ADHD."</p> <p>10 Did I read that right?</p> <p>11 A. You did.</p> <p>12 Q. Okay. And page 12 of Anand</p> <p>13 actually acknowledges that cord plasma -- and</p> <p>14 this is at page 12 -- measurements of</p> <p>15 analytes collected at birth may reflect only</p> <p>16 a snapshot of fetal metabolism. And it's</p> <p>17 difficult to draw temporal conclusions.</p> <p>18 Do you see that?</p> <p>19 A. I see that, yeah.</p> <p>20 Q. Okay. And given that</p> <p>21 acknowledgement in Anand that cord blood</p> <p>22 measurements are a snapshot and, as you</p> <p>23 discuss, right around labor and delivery, how</p> <p>24 can you exclude higher use of APAP due to a</p> <p>25 more painful or complicated labor and</p>	<p>1 showing and bolstering the causality.</p> <p>2 If we only had preclinical studies,</p> <p>3 we'd be facing the limitations of</p> <p>4 preclinical studies in isolation.</p> <p>5 We are fortunate that we have</p> <p>6 all of these things together that</p> <p>7 bolster one another.</p> <p>8 So in other words, they're</p> <p>9 right that there are limitations of</p> <p>10 the fact that there is this window,</p> <p>11 that their analytical approaches are</p> <p>12 measuring a relatively small window</p> <p>13 because of the half-life.</p> <p>14 QUESTIONS BY MR. PADGETT:</p> <p>15 Q. Would you agree that pain could</p> <p>16 be one of the, quote, "anti-stressors," end</p> <p>17 quote, that could cause oxidative stress</p> <p>18 and/or inflammatory signaling towards the end</p> <p>19 of a -- during labor or delivery?</p> <p>20 MS. HUNT: Object to form.</p> <p>21 You can answer.</p> <p>22 THE WITNESS: I'm not aware</p> <p>23 that pain causes hydroxyguanosine</p> <p>24 radicals in brain tissue.</p> <p>25 (Pearson Exhibit 80 marked for</p>
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<p>1 delivery as being responsible for why there</p> <p>2 may have been more APAP used right around the</p> <p>3 time of delivery?</p> <p>4 MS. HUNT: Object to the form</p> <p>5 of the question.</p> <p>6 You can answer.</p> <p>7 THE WITNESS: I mean, I</p> <p>8 really -- generally, I really</p> <p>9 appreciate it when observational epi</p> <p>10 folks acknowledge -- fully acknowledge</p> <p>11 the limitations of their studies, just</p> <p>12 like us experimentalists need to do.</p> <p>13 I mean, this is, again, why</p> <p>14 it's incredibly important why we look</p> <p>15 at the epidemiology alongside the</p> <p>16 preclinical studies.</p> <p>17 The preclinical studies don't</p> <p>18 suffer from that. The mice don't take</p> <p>19 medication at the end of term</p> <p>20 pregnancy for any reason. So we don't</p> <p>21 have confounding.</p> <p>22 So if epidemiology existed in</p> <p>23 isolation, these types of concerns</p> <p>24 would remain, and they would not be</p> <p>25 backed by all the preclinical studies</p>	<p>1 identification.)</p> <p>2 QUESTIONS BY MR. PADGETT:</p> <p>3 Q. Dr. Pearson, I'm going to hand</p> <p>4 you what's been marked as Exhibit 80.</p> <p>5 Do you recognize that study?</p> <p>6 A. This looks like a review</p> <p>7 article, not a study.</p> <p>8 Q. Sorry.</p> <p>9 Do you recognize that review</p> <p>10 article, Nicolini 2017? Have you reviewed</p> <p>11 that?</p> <p>12 A. I may have. I do not recall.</p> <p>13 (Pearson Exhibit 81 marked for</p> <p>14 identification.)</p> <p>15 QUESTIONS BY MR. PADGETT:</p> <p>16 Q. I'm going to hand you what's</p> <p>17 been marked as Exhibit 81 to your deposition</p> <p>18 and ask, do you recognize that review</p> <p>19 article, Kirkland 2021?</p> <p>20 A. I have looked at this before.</p> <p>21 Q. You have?</p> <p>22 A. I have.</p> <p>23 Q. And do you have any -- do you</p> <p>24 take issue with any of the conclusions in</p> <p>25 this article?</p>

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<p>1 MS. HUNT: Object to the form</p> <p>2 of the question.</p> <p>3 THE WITNESS: I would -- I</p> <p>4 would have to go through it in detail</p> <p>5 again to -- because I don't remember</p> <p>6 if I have any formal issues with</p> <p>7 anything that's raised in this.</p> <p>8 QUESTIONS BY MR. PADGETT:</p> <p>9 Q. Can you turn to page 57 of your</p> <p>10 amended report?</p> <p>11 A. Okay.</p> <p>12 Q. Do you see the part where</p> <p>13 you're talking about, there at the bottom of</p> <p>14 page 57, DNA damage being implicated in the</p> <p>15 development and progression of</p> <p>16 neurodegenerative disease like ALS,</p> <p>17 Parkinson's and Huntington's disease?</p> <p>18 A. Yes.</p> <p>19 Q. Are you -- are you analogizing</p> <p>20 ASD and ADHD to neurodegenerative diseases</p> <p>21 with average ages of onset of 55 for ALS, 60</p> <p>22 for Parkinson's, and over 65 for Alzheimer's?</p> <p>23 MS. HUNT: Object to the form</p> <p>24 of the question.</p> <p>25 You can answer.</p>	<p>1 I'm talking at therapeutic human doses.</p> <p>2 MS. HUNT: Object to the form</p> <p>3 of the question.</p> <p>4 THE WITNESS: Yeah. So the</p> <p>5 Posadas, et al. -- no, sorry, that's</p> <p>6 cortical neurons from rats, so that's</p> <p>7 not human cells.</p> <p>8 I suppose the most relevant is</p> <p>9 the Labba, et al., which is cell</p> <p>10 line -- cell line study.</p> <p>11 QUESTIONS BY MR. PADGETT:</p> <p>12 Q. The Labba, et al., 2022, is</p> <p>13 that what you're referring to?</p> <p>14 A. Yes.</p> <p>15 Q. That study involved the use of</p> <p>16 chicken granule cell neurons and human cancer</p> <p>17 cells, right?</p> <p>18 A. Yes.</p> <p>19 Q. And regardless of the cell</p> <p>20 types involved, that study involved 72 hours</p> <p>21 of steady concentrations ranging from 200</p> <p>22 micromolar to 1600 micromolar.</p> <p>23 A. 100 to 1600, yes.</p> <p>24 Q. And were there effects seen at</p> <p>25 100 micromolar? Apoptosis, specifically?</p>
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<p>1 THE WITNESS: Are you asking me</p> <p>2 if I'm drawing an analogy between ASD</p> <p>3 and ADHD and these neurodegenerative</p> <p>4 diseases?</p> <p>5 QUESTIONS BY MR. PADGETT:</p> <p>6 Q. Yes.</p> <p>7 A. I am not saying that these are</p> <p>8 the same thing, but I'm saying that these are</p> <p>9 other neurological conditions, which ASD and</p> <p>10 ADHD are. They're not neurological disorders</p> <p>11 that have DNA damage as components to them.</p> <p>12 Q. Okay. Your report discusses</p> <p>13 cell death and apoptosis, right?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. What studies support</p> <p>16 that acetaminophen at therapeutic doses</p> <p>17 causes apoptosis in human brain cells?</p> <p>18 A. Let me find it. There is a</p> <p>19 study in the -- in the -- in the in vitro</p> <p>20 section.</p> <p>21 Labba, et al., is one.</p> <p>22 Sorry, that's -- may not --</p> <p>23 that's not apoptosis, per se. That's cell</p> <p>24 death, but...</p> <p>25 Q. And while you're looking there,</p>	<p>1 A. Let me look at what they found</p> <p>2 here. Cell death was found only at the</p> <p>3 higher dose range.</p> <p>4 Q. And that's -- was that 1600 or</p> <p>5 was there -- was it seen below that?</p> <p>6 A. It was -- I think it was -- I</p> <p>7 don't recall if it was at the 1600 or if it</p> <p>8 was at the 800, but it was -- it was not at</p> <p>9 the lower doses, which would have been more</p> <p>10 physiologically relevant.</p> <p>11 Q. And is 72 hours of steady</p> <p>12 concentration of acetaminophen biologically</p> <p>13 relevant to human dosing of acetaminophen?</p> <p>14 A. I think that can be very</p> <p>15 biologically relevant.</p> <p>16 Q. Staying at a steady</p> <p>17 concentration for 72 hours from a single dose</p> <p>18 is biologically relevant?</p> <p>19 MS. HUNT: Objection. Form.</p> <p>20 You can answer.</p> <p>21 THE WITNESS: I already</p> <p>22 answered the question.</p> <p>23 This is a drug that can be</p> <p>24 given every four to six hours.</p> <p>25</p>

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<p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. Is 72 hours' steady</p> <p>3 concentration at 800 micromolar to 1600</p> <p>4 micromolar consistent with therapeutic dosing</p> <p>5 of acetaminophen?</p> <p>6 A. That latter part is not what I</p> <p>7 was saying, but I -- at 800 micromolar, I</p> <p>8 don't necessarily think that's</p> <p>9 physiologically relevant.</p> <p>10 The lower end of the dosing</p> <p>11 range I think is physiologically relevant,</p> <p>12 but steady-state in an in vitro system can be</p> <p>13 physiologically relevant.</p> <p>14 Q. But 72 hours of steady</p> <p>15 concentrations below 1800 micromolar did not</p> <p>16 show any apoptosis?</p> <p>17 A. In that study, no.</p> <p>18 Q. Do you rely on Posadas 2010 to</p> <p>19 support that acetaminophen causes apoptosis</p> <p>20 in human brain cells at therapeutic doses?</p> <p>21 A. No.</p> <p>22 Q. You have a subsection called</p> <p>23 Epigenetics. Page 60. Do you see that in</p> <p>24 your report?</p> <p>25 A. Epigenetic Changes, yes.</p>	<p>1 literature.</p> <p>2 QUESTIONS BY MR. PADGETT:</p> <p>3 Q. For example, you are not</p> <p>4 relying on the Gervin 2017 study for your</p> <p>5 weight of analysis opinions in this case?</p> <p>6 A. Gervin -- the Gervin study, I</p> <p>7 assume, is a human biospecimen study looking</p> <p>8 at epigenetics.</p> <p>9 Q. Correct.</p> <p>10 A. So then I would not have</p> <p>11 included it in my weight of evidence</p> <p>12 analysis.</p> <p>13 Q. Okay. Did you rely on it in</p> <p>14 any way in reaching your opinions in this</p> <p>15 case?</p> <p>16 MS. HUNT: Object to form.</p> <p>17 You can answer.</p> <p>18 THE WITNESS: So to the extent</p> <p>19 that the epidemiological information</p> <p>20 and evidence is part of the overall</p> <p>21 scope of this topic, it's important to</p> <p>22 the general context.</p> <p>23 But again, in forming my</p> <p>24 opinions for the weight of evidence</p> <p>25 analysis, I limited the information to</p>
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<p>1 Q. Are you relying on</p> <p>2 Dr. Baccarelli's opinions with regard to</p> <p>3 epigenetics, or have you reached your own</p> <p>4 conclusions with regard to epigenetics?</p> <p>5 You referenced Dr. Baccarelli's</p> <p>6 report here, right?</p> <p>7 A. Yes, because Dr. Baccarelli --</p> <p>8 so I do not review the observational</p> <p>9 epidemiological literature, but</p> <p>10 Dr. Baccarelli is an environmental</p> <p>11 epigeneticist and epidemiologist, so I</p> <p>12 reviewed his summary of that literature, and</p> <p>13 so I refer to that here.</p> <p>14 Q. Did you do your own independent</p> <p>15 analysis of that literature to reach your own</p> <p>16 opinion, if any, with regard to epigenetics?</p> <p>17 MS. HUNT: Object to the form</p> <p>18 of the question.</p> <p>19 You can answer.</p> <p>20 THE WITNESS: So I've seen that</p> <p>21 literature, and I'm familiar with it,</p> <p>22 but I do not use it in my weight of</p> <p>23 evidence analysis.</p> <p>24 I focus my weight of evidence</p> <p>25 analysis on the preclinical</p>	<p>1 the scope of the preclinical</p> <p>2 literature.</p> <p>3 But I have a background in</p> <p>4 epigenetics, and so I'm interested in</p> <p>5 this topic as well, but I focus on</p> <p>6 preclinical literature.</p> <p>7 QUESTIONS BY MR. PADGETT:</p> <p>8 Q. In light of your interest in</p> <p>9 epigenetics and your background, did you</p> <p>10 review the Olstad 2020 study?</p> <p>11 A. Not in detail.</p> <p>12 Q. Did you take the Olstad 2023</p> <p>13 study and its findings into account in</p> <p>14 reaching your opinions in this case?</p> <p>15 A. The weight of evidence analysis</p> <p>16 that I conducted is focused on the</p> <p>17 preclinical literature.</p> <p>18 Q. I guess I'm a little bit</p> <p>19 confused by your earlier testimony, so I'm</p> <p>20 trying to clear it up, at least in my mind.</p> <p>21 In reaching your opinions in</p> <p>22 this case, did you rely on Gervin 2017 as a</p> <p>23 basis for them?</p> <p>24 A. So I do not rely on the</p> <p>25 observational epidemiological literature to</p>

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<p style="text-align: right;">Page 274</p> <p>1 form my opinion in this case.</p> <p>2 MR. PADGETT: Take another</p> <p>3 break? I'm kind of at a breaking</p> <p>4 point.</p> <p>5 MS. HUNT: Okay.</p> <p>6 VIDEOGRAPHER: The time right</p> <p>7 now is 3:56 p.m., and we're off the</p> <p>8 record.</p> <p>9 (Off the record at 3:56 p.m.)</p> <p>10 VIDEOGRAPHER: The time right</p> <p>11 now is 4:17 p.m., and we're back on</p> <p>12 the record.</p> <p>13 QUESTIONS BY MR. PADGETT:</p> <p>14 Q. Dr. Pearson, if you turn to</p> <p>15 page 63 of your report, your amended report,</p> <p>16 you discuss brain neurotrophic factors as a</p> <p>17 mechanism.</p> <p>18 And you state there that</p> <p>19 evidence in the case demonstrates that BN --</p> <p>20 BDNF in the developing brain is altered by</p> <p>21 APAP exposure, and then you cite</p> <p>22 Blecharz-Klin 2018, Lalert 2023 and Viberg</p> <p>23 2014, correct?</p> <p>24 A. That's what it says.</p> <p>25 Q. Have animal studies on APAP</p>	<p style="text-align: right;">Page 276</p> <p>1 plausibility?</p> <p>2 MS. HUNT: Object to form.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: So you're asking</p> <p>5 whether I -- it's my assertion that</p> <p>6 studies do not need to have</p> <p>7 consistency across studies. It's not</p> <p>8 necessarily my assertion.</p> <p>9 What I'm asserting is that the</p> <p>10 particular outcome variables in</p> <p>11 studies, the directionality of the</p> <p>12 outcome variables in the studies, can</p> <p>13 be bivalent. So under certain</p> <p>14 circumstances, the directionality of</p> <p>15 the findings can be perturbed in</p> <p>16 either direction. That doesn't mean</p> <p>17 the study's relevance -- the relevance</p> <p>18 of those findings aren't important.</p> <p>19 In general, though, concordance</p> <p>20 is important when weighing the</p> <p>21 outcomes of studies in a systematic</p> <p>22 review.</p> <p>23 (Pearson Exhibits 82 and 83</p> <p>24 marked for identification.)</p> <p>25</p>
<p style="text-align: right;">Page 275</p> <p>1 reported consistent findings on altered BDNF?</p> <p>2 MS. HUNT: Object to the form.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: What is your</p> <p>5 definition of consistent?</p> <p>6 QUESTIONS BY MR. PADGETT:</p> <p>7 Q. You see a change in one area of</p> <p>8 the brain, for example, and it's replicated</p> <p>9 in another area of the brain.</p> <p>10 MS. HUNT: Object to form.</p> <p>11 You can answer.</p> <p>12 THE WITNESS: So what's being</p> <p>13 reviewed here is that all these</p> <p>14 studies see disruptions to BDNF in</p> <p>15 general. It doesn't necessarily mean</p> <p>16 that all the studies show the same</p> <p>17 exact change, necessarily, or all the</p> <p>18 same brain regions, but these studies</p> <p>19 support that BDNF is disrupted by</p> <p>20 acetaminophen.</p> <p>21 QUESTIONS BY MR. PADGETT:</p> <p>22 Q. Is it your opinion that you do</p> <p>23 not need consistency across studies assessing</p> <p>24 the same parameter in order to make a</p> <p>25 reliable conclusion regarding biologic</p>	<p style="text-align: right;">Page 277</p> <p>1 QUESTIONS BY MR. PADGETT:</p> <p>2 Q. I'm going to hand you what's</p> <p>3 been marked as Exhibit 82. Is that Viberg --</p> <p>4 the Viberg 2014 study article?</p> <p>5 A. Yes.</p> <p>6 Q. Going to hand you what's been</p> <p>7 marked as Exhibit 83.</p> <p>8 Is that the Blecharz-Klin 2018</p> <p>9 article?</p> <p>10 A. Yes.</p> <p>11 (Pearson Exhibit 84 marked for</p> <p>12 identification.)</p> <p>13 QUESTIONS BY MR. PADGETT:</p> <p>14 Q. Handing you what's been marked</p> <p>15 as Exhibit 84.</p> <p>16 Is that the Philippot 2018</p> <p>17 article discussed in your report?</p> <p>18 A. This is Philippot 2018, yes.</p> <p>19 (Pearson Exhibit 85 marked for</p> <p>20 identification.)</p> <p>21 QUESTIONS BY MR. PADGETT:</p> <p>22 Q. I'm handing you what's been</p> <p>23 marked as Exhibit 85.</p> <p>24 Is this -- and you may need to</p> <p>25 look at your report for this one. Is this</p>

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<p style="text-align: right;">Page 278</p> <p>1 Blecharz-Klin 2015 B referenced in your 2 report? 3 A. Yes. 4 (Pearson Exhibit 86 marked for 5 identification.) 6 QUESTIONS BY MR. PADGETT: 7 Q. I'm now handing you what's been 8 marked as Exhibit 86. 9 Is this the Blecharz-Klin 2016 10 report? 11 A. Yes. 12 (Pearson Exhibit 87 marked for 13 identification.) 14 QUESTIONS BY MR. PADGETT: 15 Q. Now handing you what's been 16 marked as Exhibit 87. 17 Is this the Blecharz-Klin 2019 18 study article? 19 A. Yes. 20 Q. Dr. Baccarelli {sic}, do you -- 21 is -- sorry. 22 Dr. Pearson, is Dr. Baccarelli, 23 is he considered your superior at Columbia? 24 A. He's my department chair. 25 Q. Is he -- would you characterize</p>	<p style="text-align: right;">Page 280</p> <p>1 Is it your opinion -- is it 2 your opinion that APAP affects normal 3 serotonergic signaling and function in the 4 brain during neurodevelopment? 5 A. It is among my opinion that the 6 mechanism of action that acetaminophen 7 influences in the brain is the serotonergic 8 system, and that's been supported in the 9 literature. 10 Q. And then at page 65, you 11 indicate that animal studies show that APAP 12 has an effect on serotonin function and 13 signaling in the prefrontal cortex, and you 14 start -- you cite Blecharz-Klin 2017. 15 Do you see that? 16 A. I see that. 17 Q. Was that finding consistent 18 across the other Blecharz-Klin studies that 19 looked at, for example, 5-HT signaling 20 pathways? 21 Strike that. 22 Is 5-HT signaling pathway 23 related to the serotonin function? 24 A. 5-HT is serotonin. 25 Q. Okay. So was that finding in</p>
<p style="text-align: right;">Page 279</p> <p>1 him as your boss at Columbia? 2 A. He's -- yeah. 3 Q. Okay. 4 A. Yeah, that's fair. 5 Q. Have you disclosed to Columbia 6 University that you're participating as a 7 paid expert witness in this litigation? 8 A. I have. 9 Q. Do you know whether 10 Dr. Baccarelli connected you with plaintiffs' 11 counsel? Or connected plaintiffs' counsel to 12 you? 13 MS. HUNT: Object to the form 14 of the question. 15 THE WITNESS: I do not know. 16 QUESTIONS BY MR. PADGETT: 17 Q. If you could turn to pages 64 18 to 65 of your report, your amended report. 19 You state there that -- it's a 20 section entitled "Effects on Serotonergic 21 Signaling," and you state that there -- 22 quote, "There is also evidence that APAP may 23 affect normal serotonergic signaling and 24 function in the brain during 25 neurodevelopment," end quote.</p>	<p style="text-align: right;">Page 281</p> <p>1 2017 consistent across the other 2 Blecharz-Klin studies? 3 A. The other Blecharz-Klin studies 4 looked at other regions of the brain. 5 Q. All right. And other regions 6 of the brain show no changes in 5-HT 7 signaling in, for example, Blecharz-Klin 8 2015 B, 2016 and 2019? 9 MS. HUNT: Object to the form 10 of the question. 11 You can answer. 12 THE WITNESS: So we would -- we 13 would have to look at those studies 14 one by one if we want to evaluate what 15 the serotonin effects were. 16 QUESTIONS BY MR. PADGETT: 17 Q. Sure. Let's start with 18 Blecharz-Klin 26 -- 2015 B. 19 If you turn to Table 1. 20 A. Let me see. You gave me so 21 many papers. Now I don't know which one it 22 is. 23 Which exhibit number is it? 24 Q. It's the 2015 that I recently 25 handed -- 85.</p>

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<p>1 A. 85. Thank you.</p> <p>2 Q. Was there a statistically</p> <p>3 significant change in 5-HT signaling for the</p> <p>4 P5 and P15, which is 5 milligram per kilogram</p> <p>5 and 15 milligrams per kilogram? Is that</p> <p>6 right?</p> <p>7 A. According to Table 1, there was</p> <p>8 not statistically significant changes, and</p> <p>9 this is in spinal cord.</p> <p>10 But if you look at P15, there's</p> <p>11 quite a substantial increase. It goes from</p> <p>12 88, and the units here are -- I don't see --</p> <p>13 nanograms per grams tissue, all the way up to</p> <p>14 107 nanograms per gram.</p> <p>15 So biologically significant</p> <p>16 increase, but not statistically significant</p> <p>17 increase.</p> <p>18 Q. What do you mean by a</p> <p>19 biologically significant increase?</p> <p>20 A. Well, potentially biologically</p> <p>21 meaningful, but not significantly reliably</p> <p>22 increased.</p> <p>23 Q. Okay. If you could turn to</p> <p>24 Blecharz-Klin --</p> <p>25 A. I'm sorry, that was -- I'll</p>	<p>1 not statistically significant.</p> <p>2 The metabolite, the primary</p> <p>3 metabolite, 5-HIAA is significantly different</p> <p>4 between groups.</p> <p>5 And there's trends towards</p> <p>6 differences in the 5-HIAA/5-HT ratio, which</p> <p>7 is a utilization ratio, not statistically</p> <p>8 significant.</p> <p>9 Q. 5-HT was not statistically</p> <p>10 significant. And then even you're talking</p> <p>11 from an increase from 5-HT from control to P5</p> <p>12 to P15, there's not a dose response from P5</p> <p>13 to P15, correct?</p> <p>14 MS. HUNT: Object to the form</p> <p>15 of the question.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: Well, there's an</p> <p>18 inverted U-dose response, so I don't</p> <p>19 know what you mean by not a dose</p> <p>20 response. There's still a dose</p> <p>21 response.</p> <p>22 QUESTIONS BY MR. PADGETT:</p> <p>23 Q. Sorry. If you'd turn to</p> <p>24 Blecharz 2019, which is Exhibit 87, I</p> <p>25 believe.</p>
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<p>1 clarify.</p> <p>2 That was in 5-HIAA, which is a</p> <p>3 metabolite of serotonin. So I was reading</p> <p>4 the wrong line. I was reading below</p> <p>5 serotonin. I would caveat that. I was</p> <p>6 reading the wrong line.</p> <p>7 Q. Serotonin is not bio -- did not</p> <p>8 show statistically significant changes?</p> <p>9 A. Serotonin didn't, but --</p> <p>10 serotonin, actually 5-HT, showed a linear</p> <p>11 trend upwards --</p> <p>12 Q. Okay.</p> <p>13 A. -- even it wasn't significantly</p> <p>14 increased.</p> <p>15 Q. If you could turn to</p> <p>16 Blecharz-Klin 2016.</p> <p>17 A. 2016.</p> <p>18 Q. And that is exhibit --</p> <p>19 A. 86, looks like.</p> <p>20 Q. 86?</p> <p>21 If you could turn to page 1161.</p> <p>22 A. Okay.</p> <p>23 Q. Table 1.</p> <p>24 A. Yeah. So there serotonin is up</p> <p>25 at the 5 milligrams per kilogram dose, but</p>	<p>1 If you look at Table 1, the</p> <p>2 serotonin levels were not -- there were no</p> <p>3 statistically significant differences for</p> <p>4 control P5 or P15, correct?</p> <p>5 A. There are no statistically</p> <p>6 significant differences here, and this is in</p> <p>7 the hypothalamus. Different brain region.</p> <p>8 (Pearson Exhibit 88 marked for</p> <p>9 identification.)</p> <p>10 QUESTIONS BY MR. PADGETT:</p> <p>11 Q. Okay. Dr. Pearson, I'm going</p> <p>12 to hand you what's been marked as Exhibit 90</p> <p>13 and -- strike that.</p> <p>14 I'm going to hand you what's</p> <p>15 been marked as Exhibit 88 and represent to</p> <p>16 you that this is a -- sorry.</p> <p>17 Do you ever -- do you refer to</p> <p>18 the NIH as an authoritative body or</p> <p>19 organization with regard to standards of</p> <p>20 conducting scientific research?</p> <p>21 MS. HUNT: Object to the form</p> <p>22 of the question.</p> <p>23 You can answer.</p> <p>24 THE WITNESS: The NIH on the</p> <p>25 whole, that's a fairly broad category.</p>

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<p>1 The NIH is a really, really widespread 2 organization that is involved in 3 funding research and conducting 4 research. 5 NIH has organizations within it 6 that has very, very specific standards 7 for compliance within research, so I 8 would say many of those organizations 9 I would look to as authorities on 10 research compliance and research 11 ethics, if that's what you're asking 12 about, yeah. 13 QUESTIONS BY MR. PADGETT: 14 Q. I'm going to represent to you 15 that Exhibit 88 is off the NIH website, 16 specifically a section on grants and funding, 17 NIH central resource for grants and funding 18 and for information. 19 Are you familiar with that 20 document? Or that part of the NIH website? 21 A. I'm familiar that the NIH, 22 through their grants offices, has these sorts 23 of offices on rigor and transparency and 24 research in funding, yes. 25 MS. HUNT: I'm sorry, I would</p>	<p>1 and design their own research accordingly. 2 So we don't want to misconstrue 3 what's being stated here. They're not saying 4 that for -- in order for research to be 5 considered reliable, that every single data 6 point in everybody else's research has to be 7 replicated in exactly the same way for it to 8 be considered reliable. It's false 9 equivalence. 10 Q. In the second -- and then 11 the -- a sentence two -- two more after that 12 one that we just discussed, it says, quote, 13 "When a result can be reproduced by multiple 14 scientists, it validates the original results 15 and readiness to progress to the next phase 16 of research," period, end quote. 17 Do you agree with that 18 statement? 19 A. I agree with that statement. 20 But what defines a result 21 doesn't mean that the result is -- that the 22 study is performed in exactly the same way 23 and the datum, or the exact data point, is 24 exactly the same thing. 25 Q. At pages 65 to 66 of your</p>
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<p>1 just object. I'm not sure this is a 2 complete exhibit. 3 QUESTIONS BY MR. PADGETT: 4 Q. On the second page of that 5 exhibit it states, quote, "Two of the 6 cornerstones of science advancement are rigor 7 in designing and performing scientific 8 research and the ability to reproduce 9 biomedical research findings," period, end 10 quote. 11 Do you agree with that 12 statement? 13 A. I certainly agree with that 14 statement. 15 But I want to extend this. 16 This isn't referring to the fact that 17 individual data points within research 18 studies have to be reproduced in order for 19 the research to be reliable. 20 They're referring to the fact 21 that people need to be transparent about the 22 way that they conduct their research so that 23 other people can perform work similarly, or 24 understand the way that people have performed 25 their research, so that they can follow up</p>	<p>1 report, you discuss prostaglandins? 2 A. Yes. 3 Q. You state that -- there on -- 4 it's on page 66 -- that APAP's effects on 5 prostaglandins are likely interconnected with 6 other processes and also affected by APAP, 7 and then you reference AM404 again. 8 Is it your opinion that any 9 alleged effects on prostaglandins are the 10 result of the AM404 metabolite? 11 MS. HUNT: Object to the form 12 of the question. 13 You can answer. 14 THE WITNESS: That is not 15 what's meant by this paragraph. 16 QUESTIONS BY MR. PADGETT: 17 Q. What is meant by that paragraph 18 in the reference to AM404? 19 A. So what's meant here is that 20 acetaminophen's actions, mode of action, with 21 respect to antinociceptive effects can 22 involve prostaglandins. Its effects on 23 neurodevelopment can also involve 24 prostaglandins. 25 It's also saying that</p>

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<p>1 acetaminophen can act through AM404 and the</p> <p>2 endocannabinoid system and that these two</p> <p>3 path -- these different pathways can also</p> <p>4 intersect with each other. But it's not</p> <p>5 saying that prostaglandins necessarily</p> <p>6 involve AM404.</p> <p>7 Q. Is an increase -- and you talk</p> <p>8 about spinophilin in the -- I think it was</p> <p>9 the...</p> <p>10 A. Oh, cealix {phonetic}</p> <p>11 spinophilin, yeah.</p> <p>12 Q. Yes.</p> <p>13 A. A protein, yeah.</p> <p>14 Q. Is it your opinion that an</p> <p>15 increase in spinophilin is a change seen in</p> <p>16 ASD or ADHD brains that has been accepted in</p> <p>17 the scientific community as a cause of ASD or</p> <p>18 ADHD?</p> <p>19 A. Changes in synaptics, dendritic</p> <p>20 spines has been seen as sa pathological</p> <p>21 hallmark in a number of neurodevelopmental</p> <p>22 disorders, including ASD. But that</p> <p>23 particular protein isn't necessarily a</p> <p>24 diagnostic feature of those particular</p> <p>25 neurodevelopmental disorders.</p>	<p>1 be a plausible biomech -- mechanism --</p> <p>2 biological mechanism of ASD or ADHD?</p> <p>3 MS. HUNT: Object to the form</p> <p>4 of the question.</p> <p>5 You can answer.</p> <p>6 THE WITNESS: My recollection</p> <p>7 is the vermis area of the cerebellum</p> <p>8 is just an interfaced area of the</p> <p>9 cerebellum, but I don't have deep</p> <p>10 expertise about the vermis itself of</p> <p>11 the cerebellum.</p> <p>12 As I mentioned, the cerebellum</p> <p>13 is a very involved, very rich area of</p> <p>14 the brain that's -- that has very</p> <p>15 diverse functions.</p> <p>16 I think Dr. Hollander would be</p> <p>17 able to give a much more direct and</p> <p>18 complete answer to that.</p> <p>19 MR. PADGETT: We can take a</p> <p>20 short break. I may be near about</p> <p>21 done. The break may help facilitate</p> <p>22 that.</p> <p>23 MS. HUNT: Party on.</p> <p>24 VIDEOGRAPHER: The time right</p> <p>25 now is 4:43 p.m., and we're off the</p>
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<p>1 And that particular protein</p> <p>2 that you're discussing is involved in</p> <p>3 plasticity of dendritic spines.</p> <p>4 Q. What is the function of the</p> <p>5 cerebellar vermis area of the brain?</p> <p>6 A. The cerebellar vermis is just</p> <p>7 one anatomical location within the</p> <p>8 cerebellum.</p> <p>9 The cerebellum in general is</p> <p>10 involved in a lot of functions, in motor</p> <p>11 behaviors, cognitive behaviors. It's</p> <p>12 recently been learned to be involved in a lot</p> <p>13 of emotional-related functions as well.</p> <p>14 The vermis area of the</p> <p>15 cerebellum is -- I'm not particularly up on</p> <p>16 what it's actually involved with, but in</p> <p>17 general, again, the cerebellum has diverse</p> <p>18 functions ranging from emotion to cognition.</p> <p>19 And its involvement in ASD and</p> <p>20 ADHD is -- is well -- it's linked to both</p> <p>21 conditions.</p> <p>22 Q. I'm talking about specifically</p> <p>23 the cerebellar vermis area of the brain.</p> <p>24 Do you know whether that --</p> <p>25 changes in that region have -- are thought to</p>	<p>1 record.</p> <p>2 (Off the record at 4:43 p.m.)</p> <p>3 VIDEOGRAPHER: The time right</p> <p>4 now is 5:07 p.m., and we're back on</p> <p>5 the record.</p> <p>6 MR. PADGETT: At this time we</p> <p>7 have no further questions and pass the</p> <p>8 witness.</p> <p>9 CROSS-EXAMINATION</p> <p>10 QUESTIONS BY MS. HUNT:</p> <p>11 Q. I just have a few questions.</p> <p>12 Dr. Pearson, you testified</p> <p>13 earlier that you were contacted by</p> <p>14 plaintiffs' counsel sometime in 2022.</p> <p>15 Is that right?</p> <p>16 A. That's right. I stated that I</p> <p>17 was contacted -- well, my answer shifted a</p> <p>18 little bit. I initially said 2023, and then</p> <p>19 I said 2022. I was a little bit confused.</p> <p>20 Thinking about it more, I was</p> <p>21 initially contacted more accurately in June</p> <p>22 of 2022, but I didn't actually start working</p> <p>23 with plaintiffs' counsel until --</p> <p>24 substantively until February of 2023. That's</p> <p>25 when I started having billable work.</p>

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<p>1 Q. Okay. And did any lawyer have</p> <p>2 input on the analysis or the conclusions of</p> <p>3 your study, Baker 2023?</p> <p>4 A. No.</p> <p>5 Q. And were you completely</p> <p>6 objective in rendering the results of your</p> <p>7 study?</p> <p>8 A. Yes.</p> <p>9 Q. Have you ever authored or</p> <p>10 worked on any studies at the behest of</p> <p>11 lawyers?</p> <p>12 A. No.</p> <p>13 Q. Dr. Pearson, do you recall your</p> <p>14 earlier testimony about translationally</p> <p>15 relevant APAP doses used in rodent studies?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And in general, is the</p> <p>18 translationally relevant dose for mice</p> <p>19 different than the translationally relevant</p> <p>20 dose for rats?</p> <p>21 A. Mice and rats have different</p> <p>22 sensitivities to acetaminophen</p> <p>23 administration, so the answer to that would</p> <p>24 be to the affirmative. They can have</p> <p>25 different translationally relevant doses.</p>	<p>1 what has informed your work both in this</p> <p>2 litigation and outside of it?</p> <p>3 A. Yes.</p> <p>4 So to add on to that, so</p> <p>5 Dr. Baccarelli's expert report, which I</p> <p>6 reviewed and rely upon for my expert report,</p> <p>7 he uses the Bradford Hill approach. And the</p> <p>8 other approach that he uses, I rely upon that</p> <p>9 in my expert report. But also the</p> <p>10 epidemiological literature that he's</p> <p>11 reviewed, that also informs the scientific</p> <p>12 research that I perform.</p> <p>13 So not his expert report, per</p> <p>14 se, but I'm just saying the epidemiological</p> <p>15 findings that acetaminophen is linked to</p> <p>16 these neurodevelopmental outcomes. I would</p> <p>17 not be performing preclinical literature --</p> <p>18 preclinical research if there wasn't these</p> <p>19 findings themselves.</p> <p>20 MS. HUNT: I have no more</p> <p>21 questions.</p> <p>22 VIDEOGRAPHER: Off the record?</p> <p>23 MR. PADGETT: Off the record.</p> <p>24 VIDEOGRAPHER: The time right</p> <p>25 now --</p>
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<p>1 Q. Okay. Can we turn to page 83</p> <p>2 of your expert report? I think that should</p> <p>3 be...</p> <p>4 A. Yes.</p> <p>5 Q. Yes.</p> <p>6 Dr. Pearson, can you tell me</p> <p>7 what animal was used in the Beck 2001 study?</p> <p>8 A. Rats.</p> <p>9 Q. How about Lichtensteiger 2015?</p> <p>10 A. Rats.</p> <p>11 Q. How about Klein 2020?</p> <p>12 A. Rat.</p> <p>13 Q. How about Rigobello 2021?</p> <p>14 A. Also rats.</p> <p>15 Q. And in your expert opinion, did</p> <p>16 these rat studies use translationally</p> <p>17 relevant APAP doses?</p> <p>18 A. Yes.</p> <p>19 Q. Finally, Dr. Pearson, did you</p> <p>20 rely on Dr. Baccarelli's opinions in terms of</p> <p>21 his review of the human epidemiological</p> <p>22 studies in rendering your opinion?</p> <p>23 A. I did.</p> <p>24 Q. And is the epidemiological</p> <p>25 literature analyzed by Dr. Baccarelli part of</p>	<p>1 MR. PADGETT: Can I take a</p> <p>2 break? A short break?</p> <p>3 VIDEOGRAPHER: The time right</p> <p>4 now is 5:10 p.m., and we're off the</p> <p>5 record.</p> <p>6 (Off the record at 5:10 p.m.)</p> <p>7 VIDEOGRAPHER: The time right</p> <p>8 now is 5:15 p.m., and we're back on</p> <p>9 the record.</p> <p>10 REDIRECT EXAMINATION</p> <p>11 QUESTIONS BY MR. PADGETT:</p> <p>12 Q. Dr. Pearson, you used mice as</p> <p>13 the animal in the Baker 2023 study, correct?</p> <p>14 A. That is correct.</p> <p>15 Q. Okay. And you mentioned</p> <p>16 something about mice and rats having</p> <p>17 different sensitivities to APAP during</p> <p>18 Ms. Hunt's questioning.</p> <p>19 Do you recall that?</p> <p>20 A. Yes, I recall that.</p> <p>21 Q. Okay. Do you believe that mice</p> <p>22 are a better model in terms of equivalency to</p> <p>23 humans in terms of animal research on</p> <p>24 acetaminophen?</p> <p>25 MS. HUNT: Object to the form</p>

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<p style="text-align: right;">Page 298</p> <p>1 of the question.</p> <p>2 You can answer.</p> <p>3 THE WITNESS: I think that both</p> <p>4 mice and rats are suitable for this</p> <p>5 line of research.</p> <p>6 What I was stating before is</p> <p>7 that mice and rats have different</p> <p>8 sensitivity to hepatotoxic doses of</p> <p>9 acetaminophen.</p> <p>10 QUESTIONS BY MR. PADGETT:</p> <p>11 Q. Is the sensitivity for mice</p> <p>12 more akin to humans with regard to</p> <p>13 acetaminophen than rats compared to humans?</p> <p>14 MS. HUNT: Object to the form</p> <p>15 of the question.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: I've seen in the</p> <p>18 literature some people have said that</p> <p>19 mice can be more sensitive to modeling</p> <p>20 hepatotoxicity because lower doses of</p> <p>21 acetaminophen will cause</p> <p>22 hepatotoxicity in mice than rats.</p> <p>23 In other words, it takes a</p> <p>24 higher dose -- it can, depending on</p> <p>25 the strain and the circumstances, it</p>	<p style="text-align: right;">Page 300</p> <p>1 CERTIFICATE</p> <p>2 I, CARRIE A. CAMPBELL, Registered</p> <p>3 Diplomat Reporter, Certified Realtime</p> <p>4 Reporter and Certified Shorthand Reporter, do</p> <p>5 hereby certify that prior to the commencement</p> <p>6 of the examination, Brandon Pearson, MS,</p> <p>7 Ph.D., was duly sworn by me to testify to the</p> <p>8 truth, the whole truth and nothing but the</p> <p>9 truth.</p> <p>10 I DO FURTHER CERTIFY that the</p> <p>11 foregoing is a verbatim transcript of the</p> <p>12 testimony as taken stenographically by and</p> <p>13 before me at the time, place and on the date</p> <p>14 hereinbefore set forth, to the best of my</p> <p>15 ability.</p> <p>16 I DO FURTHER CERTIFY that I am</p> <p>17 neither a relative nor employee nor attorney</p> <p>18 nor counsel of any of the parties to this</p> <p>19 action, and that I am neither a relative nor</p> <p>20 employee of such attorney or counsel, and</p> <p>21 that I am not financially interested in the</p> <p>22 action.</p> <p>23</p> <p>24</p> <p>25</p> <p>CARRIE A. CAMPBELL, NCRA Registered Diplomat Reporter Certified Realtime Reporter California Certified Shorthand Reporter #13921 Missouri Certified Court Reporter #859 Illinois Certified Shorthand Reporter #084-004229 Texas Certified Shorthand Reporter #9328 Kansas Certified Court Reporter #1715 New Jersey Certified Court Reporter #30X100242600 Louisiana Certified Court Reporter #2021012 Notary Public Dated: August 14, 2023</p>
<p style="text-align: right;">Page 299</p> <p>1 can take a higher dose of</p> <p>2 acetaminophen in a rat to cause</p> <p>3 hepatotoxicity than a mouse.</p> <p>4 But that does not mean it's a</p> <p>5 better model for understanding</p> <p>6 acetaminophen neurotoxicity, for</p> <p>7 instance. Both species can be</p> <p>8 suitable to understand neurotoxicity</p> <p>9 of acetaminophen.</p> <p>10 MR. PADGETT: That's all the</p> <p>11 questions I have. Thank you for your</p> <p>12 time today.</p> <p>13 THE WITNESS: Thank you.</p> <p>14 VIDEOGRAPHER: The time right</p> <p>15 now is 5:18 p.m., and we're off the</p> <p>16 record.</p> <p>17 (Deposition concluded at 5:18 p.m.)</p> <p>18 -----</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 301</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over</p> <p>4 carefully and make any necessary corrections.</p> <p>5 You should state the reason in the</p> <p>6 appropriate space on the errata sheet for any</p> <p>7 corrections that are made.</p> <p>8 After doing so, please sign the</p> <p>9 errata sheet and date it. You are signing</p> <p>10 same subject to the changes you have noted on</p> <p>11 the errata sheet, which will be attached to</p> <p>12 your deposition.</p> <p>13 It is imperative that you return</p> <p>14 the original errata sheet to the deposing</p> <p>15 attorney within thirty (30) days of receipt</p> <p>16 of the deposition transcript by you. If you</p> <p>17 fail to do so, the deposition transcript may</p> <p>18 be deemed to be accurate and may be used in</p> <p>19 court.</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<div>Page 302</div> <div>1 ACKNOWLEDGMENT OF DEPONENT</div> <div>2</div> <div>3</div> <div>4 I, _____, do</div> <div>5 hereby certify that I have read the foregoing</div> <div>6 pages and that the same is a correct</div> <div>7 transcription of the answers given by me to</div> <div>8 the questions therein propounded, except for</div> <div>9 the corrections or changes in form or</div> <div>10 substance, if any, noted in the attached</div> <div>11 Errata Sheet.</div> <div>12</div> <div>13 _____</div> <div>14 Brandon Pearson, MS, Ph.D. DATE</div> <div>15</div> <div>16 Subscribed and sworn to before me this</div> <div>17 _____ day of _____, 20 ____.</div> <div>18 My commission expires: _____</div> <div>19 Notary Public</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> <div>25</div>	<div>Page 304</div> <div>1 -----</div> <div>2 LAWYER'S NOTES</div> <div>3 -----</div> <div>4 PAGE LINE</div> <div>5 _____</div> <div>6 _____</div> <div>7 _____</div> <div>8 _____</div> <div>9 _____</div> <div>10 _____</div> <div>11 _____</div> <div>12 _____</div> <div>13 _____</div> <div>14 _____</div> <div>15 _____</div> <div>16 _____</div> <div>17 _____</div> <div>18 _____</div> <div>19 _____</div> <div>20 _____</div> <div>21 _____</div> <div>22 _____</div> <div>23 _____</div> <div>24 _____</div> <div>25 _____</div>
<div>Page 303</div> <div>1 -----</div> <div>2 ERRATA</div> <div>3 -----</div> <div>4 PAGE LINE CHANGE</div> <div>5 _____</div> <div>6 _____</div> <div>7 _____</div> <div>8 _____</div> <div>9 _____</div> <div>10 _____</div> <div>11 _____</div> <div>12 _____</div> <div>13 _____</div> <div>14 _____</div> <div>15 _____</div> <div>16 _____</div> <div>17 _____</div> <div>18 _____</div> <div>19 _____</div> <div>20 _____</div> <div>21 _____</div> <div>22 _____</div> <div>23 _____</div> <div>24 _____</div> <div>25 _____</div>	

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